United States of America

Confidence Building Measure Return covering 2010

Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction

Submitted to the United Nations on
April 15, 2011

Declaration form on Nothing to Declare or Nothing New to Declare for use in the information exchange

Measure	Nothing to declare	Nothing new to declare
A, Part 2 (i)		
A, Part 2 (ii)		
A, Part 2 (iii)		
B (i)		
B (ii)		
C		
D		
E		
F		√
G		

Date: April 15, 2011

State Party to the Convention: United States of America

April 15, 2011

Report of the United States of America to the United Nations Department for Disarmament Affairs

Pursuant to the procedural modalities agreed upon in April 1987 at the "Ad Hoc Meeting of Scientific and Technical Experts for STATES Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction," the United States of America submits the following information under Article V of the Convention:

Confidence Building Measure A, Part 1

Exchange of data on research centres and laboratories — pages 4-20

Confidence Building Measure A, Part 2

Exchanges of information on national biological defence research and development programmes

(i) Declaration — pages 22-23
(ii) Description — pages 24-58
(iii) Facilities — pages 59-225

Confidence Building Measure B

Exchange of information on all outbreaks of infectious diseases and similar occurrences caused by toxins

(i) Background Information — pages 227-235
(ii) Information on occurrences that seem to deviate from the norm — pages 236-243

Confidence Building Measure C

Encouragement of publication of results and promotion of use of knowledge — pages 244- 250

Confidence Building Measure D

Active promotion of contacts — pages 251- 265

Confidence Building Measure E

Declaration of legislature, regulations, and other measures — pages 266- 272

Confidence Building Measure F

Declaration of past activities in offensive and/or defensive biological research and development programmes — pages 273, 274

Confidence Building Measure G

Declaration of vaccine production facilities — pages 275-284

Appendix A

List of the Biological Select Agents and Toxins, and NIAID Category A, B and C Priority Pathogens — pages 285-289

Appendix B

Compiled list of biological agents and toxins used for biodefense research — pages 290-296

Form A, Part 1

BWC - Confidence Building Measure

Exchange of data on research centres and laboratories

United States of America

April 15, 2011

Form A, Part 1

Exchange of data on research centres and laboratories

In accordance with the agreement at the Third Review Conference that States Parties provide data on "research centres and laboratories that meet very high national or international safety standards established for handling, for permitted purposes, biological materials that pose a high individual and community risk or specialize in permitted biological activities directly related to the Convention," the United States is providing data on all facilities designated biosafety level 4 (BSL-4) that were operational during 2010. Data on BSL-4 facilities currently under construction, including two at the National Interagency Biodefense Campus in Frederick Maryland, will be included in future U.S. CBM submissions beginning with the submission covering the year each such facility becomes operational. Of these two facilities, the National Biodefense Analysis and Countermeasures Center (NBACC) began operating its BSL-2 Laboratory space in November 2010 (and is reported in Form A Part 2(iii)).

In addition to the BSL-4 facilities described above, the United States is providing data on Plum Island Animal Disease Center (PIADC) due to its historical significance.

Form A, Part 1

Exchange of data on research centres and laboratories[1]

1. **Name(s) of facility[2]**

   Viral Immunology Center - National B Virus Resource Laboratory

2. **Responsible public or private organization or company.**

   Georgia State University

3. **Location and postal address.**

   P. O. Box 4118
   Atlanta, Georgia 30302-4118
   United States

4. **Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

   U.S. Department of Defense (DOD)
   National Institutes of Health (NIH)
   Georgia Research Alliance

5. **Number of maximum containment units[3] within the research center and/or laboratory, with an indication of their respective size (m^2).**

   BSL 4 Laboratory 60 m^2

6. **If no maximum containment unit, indicate highest level of protection.**

   Not applicable

7. **Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

   The Viral Immunology Center provides a global resource to assist in the identification of zoonotic disease transmissions and to develop enhanced strategies to detect viral infections in macaques. Current projects in the National B Virus Resource Laboratory are focused on the molecular biology of human and non-human primate alphaherpesviruses and the diseases

[1] The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.
[2] For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".
[3] In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent

they cause. Studies focus on the mechanisms by which virus kills the host and how that process can be circumvented with:

- **early identification -** research focuses on the design and development of new approaches to more effectively identify these agents in both natural and foreign hosts;
- **appropriate antiviral drugs -** researchers continually screen the efficacy of existing as well as novel antiviral agents to inhibit the growth of viruses that can potentially cross into the human population, either through occupational exposure or through more subtle contact; and
- **in the future, effective vaccines**.

Additional information can be found at:
http://www2.gsu.edu/~wwwvir/Research/Index.html

Form A, Part 1

Exchange of data on research centres and laboratories[1]

1. **Name(s) of facility[2]**

   The Betty Slick and Lewis J. Moorman, Jr. Laboratory Complex, Department of Virology and Immunology

2. **Responsible public or private organization or company.**

   Southwest Foundation for Biomedical Research

3. **Location and postal address.**

   P.O. Box 760549
   San Antonio, Texas 78245-0549
   United States

   Note: As of February 1, 2011 the company name has changed from Southwest Foundation for Biomedical Research to Texas Biomedical Research Institute.

4. **Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

   National Institutes of Health (NIH)
   U.S. Department of Defense (DOD)
   U.S. Department of Homeland Security (DHS)
   Private Sector Companies
   Private Donors

5. **Number of maximum containment units[3] within the research center and/or laboratory, with an indication of their respective size (m^2).**

   BSL 4 Laboratory 114 m^2

6. **If no maximum containment unit, indicate highest level of protection.**

   Not applicable

7. **Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

---

[1] The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.
[2] For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".
[3] In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent.

The mission of the Department is: "Through basic and applied research, develop vaccines and therapeutics against viral pathogens, and determine how viruses replicate and spread." In the BSL-4 laboratory, scientists are studying new and emerging disease threats, possible bioterrorism agents, as well as unknown agents for which there is not a biosafety classification. TXBiomed (formerly Southwest Foundation for Biomedical Research) has permits from the U.S. Department of Agriculture and the Centers for Disease Control to work on select agents as designated by the CDC.

Additional information can be found at:
http://www.TXBiomed.org

Form A, Part 1

Exchange of data on research centres and laboratories[1]

1. **Name(s) of facility[2]**

   Galveston National Laboratory (GNL) Complex including Robert E. Shope Laboratory

2. **Responsible public or private organization or company.**

   The University of Texas Medical Branch

3. **Location and postal address.**

   301 University Blvd.
   Galveston, Texas 77555
   United States

4. **Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

   National Institutes of Health (NIH)
   U.S. Department of Homeland Security (DHS)
   U.S. Department of Defense (DOD)
   U.S. Department of Energy (DOE)
   Pharmaceutical Industry
   Private Foundations
   U.S. Department of Agriculture (USDA)
   Universities

5. **Number of maximum containment units[3] within the research center and/or laboratory, with an indication of their respective size (m^2).**

BSL 4 Laboratory	186 m^2	Shope laboratory
BSL 4 Laboratory	1022 m^2	GNL laboratory

6. **If no maximum containment unit, indicate highest level of protection.**

   Not applicable

7. **Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

[1] The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.
[2] For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".
[3] In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent.

The mission of the Galveston National Laboratory is to assist the National Institute of Allergy and Infectious Diseases and the nation in the development of an improved means for the prevention, diagnosis and treatment of potentially life-threatening diseases caused by naturally emerging and purposefully disseminated infectious agents. To accomplish this goal GNL conducts multidisciplinary research into the causes, modes of transmission, and mechanisms of infectious diseases. Studies focus on a number of pathogens requiring BSL-4 containment, primarily those that cause viral hemorrhagic fevers, as well as some zoonotic viruses requiring enhanced BSL-3 containment. Products likely to emerge from research and investigations within the GNL include novel diagnostic assays, improved therapeutics and treatment models, and preventative measures such as vaccines.

Additional information can be found at:
http://www.utmb.edu/gnl/

Form A, Part 1

Exchange of data on research centres and laboratories[1]

1. **Name(s) of facility[2]**

   Plum Island Animal Disease Center (PIADC)

   Declared in accordance with Form A, Part 2 (iii)

2. **Responsible public or private organization or company.**

   U.S. Department of Homeland Security
   Science and Technology Directorate
   Office of National Laboratories

3. **Location and postal address.**

   DHS PIADC
   P.O. Box 848
   Greenport, New York 11944-0848
   United States

   40550 Rte. 25 Orient Point, NY 11957

4. **Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

   U.S. Department of Homeland Security (DHS)
   U.S. Department of Agriculture (USDA)

5. **Number of maximum containment units[3] within the research center and/or laboratory, with an indication of their respective size (m^2).**

Enhanced BSL 3 Laboratory	2630 m^2	Lab Space
Enhanced BSL 3 Laboratory	2961 m^2	Animal Room Space
Enhanced BSL 3 Laboratory	12052 m^2	Support Space

[1] The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.
[2] For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".
[3] In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent.

6. If no maximum containment unit, indicate highest level of protection.

The Center has the following features required for a BSL-3 facility: Restricted access into the laboratory facility; use of Class II Biological Safety Cabinets (BSCs) or other physical containment devices during the manipulation of infectious materials; placement of a foot-operated sink for hand washing in each laboratory zone; sealed laboratory windows; ducted air ventilation system that provides sustained directional airflow within the laboratory from areas of lower potential contamination to areas of higher potential contamination and is design so that under failure conditions airflow is not reversed; and all filter housings (HEPA and deep-bed) have isolation dampers and decontamination ports.

The Center has the following features which represent an enhancement of BSL-3 space: biowaste thermal treatment plant; clothing change and shower facilities; double door autoclaves at building exit zones; inflatable APR doors throughout the containment facility to provide laboratory isolation; all animal isolation rooms are entered through inflatable APR doors with all occupied animal isolation rooms having a change-in and shower-out requirement; laboratory and animal biocontainment room areas are HEPA filtered exhaust air, some laboratory and animal room areas are HEPA filtered in and out, and a limited number of animal rooms in BSL-3 biocontainment are deep-bed filtered exhaust air (non-infectious animal work); incinerators for pathological waste disposal; automatically activated emergency power source (generators) for the laboratory exhaust system, alarms, lighting, entry and exit controls, BSCs and freezers; all door air gaskets have a check valve in case of loss of power and the ability to be tied into an available backup compressor; and placement of monitoring and controls systems for air supply, exhaust, alarms, entry and exit controls and security systems on an uninterrupted power supply (UPS), currently only newer air supply and exhaust units are placed on an UPS, with plans for older units to be retrofitted with UPSs.

The Center lacks the following features required for BSL-4 biocontainment: Class III gas-tight glove box hoods within enhanced BSL-3 containment space and / or ventilated positive pressure personnel safety suits and safety suit room within biocontainment space; personnel suit chemical decontamination airlocks; check valve systems on gas and fluid supply piping; independent dedicated waste water decontamination unit for BSL-4 zone; HEPA in and double (in series) HEPA exhaust ventilation; an automatically activated emergency power source for life support systems; and placement of monitoring and controls systems for life support on an UPS.

7. Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.

PIADC provides the only research and confirmatory diagnostic capability for specific high-consequence, contagious, foreign animal diseases of livestock. The focus of the research is on pathogens that infect animals, not those of humans. The facility maintains a reference repository of animal disease agents (and diagnostic capabilities to recognize them should they occur in the U.S.). The facility also trains veterinarians to field diagnose high

consequence foreign animal disease.

Additional information can be found at:
http://www.dhs.gov/files/labs/editorial_0901.shtm
http://www.ars.usda.gov/AboutUs/AboutUs.htm?modecode=19-40-00-00
http://www.ars.usda.gov/research/projects_programs.htm?modecode=19-40-00-00
http://www.aphis.usda.gov/animal_health/lab_info_services/about_faddl.shtml

Form A, Part 1

Exchange of data on research centres and laboratories[1]

1. **Name(s) of facility[2]**

   U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

   Declared in accordance with Form A, Part 2 (iii)

2. **Responsible public or private organization or company.**

   U.S. Army Medical Research and Materiel Command

3. **Location and postal address.**

   1425 Porter Street
   Fort Detrick
   Frederick, Maryland 21702-5011
   United States

4. **Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

   U.S. Department of Defense (DOD)

5. **Number of maximum containment units[3] within the research center and/or laboratory, with an indication of their respective size (m^2).**

   BSL 4 Laboratory 1093 m^2

6. **If no maximum containment unit, indicate highest level of protection.**

   Not Applicable

7. **Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

   USAMRIID conducts research to develop strategies, products, information, procedures and training programs for medical defense against biological warfare threats and infectious diseases. Medical products developed to protect military personnel against biological agents

[1] The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.
[2] For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".
[3] In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent.

include vaccines, drugs, diagnostic capabilities and various medical management procedures.

Additional information can be found at:
http://www.usanriid.army.mil/

Form A, Part 1

Exchange of data on research centres and laboratories[1]

1. **Name(s) of facility[2]**

   CDC, Office of Infectious Diseases (OID)

   Declared in accordance with Form A, Part 2 (iii)

2. **Responsible public or private organization or company.**

   Centers for Disease Control and Prevention
   U.S. Department of Health and Human Services

3. **Location and postal address.**

   1600 Clifton Road N.E.
   Atlanta, Georgia 30333
   United States

4. **Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

   U.S. Department of Health and Human Services (HHS)
   U.S. Department of Homeland Security (DHS)
   U.S. Environmental Protection Agency (EPA)
   Other Governmental Agencies

5. **Number of maximum containment units[3] within the research center and/or laboratory, with an indication of their respective size (m^2).**

   BSL 4 Laboratory 198 m^2
   BSL 4 Laboratory 221 m^2
   BSL 4 Laboratory 135 m^2
   BSL 4 Laboratory 135 m^2
   BSL 4 Laboratory 135 m^2
   BSL 4 Laboratory 135 m^2

[1] The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.
[2] For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".
[3] In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent.

6. **If no maximum containment unit, indicate highest level of protection.**

   Not Applicable

7. **Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

   Activities include developing diagnostic assays for public health, conducting molecular and antigenic characterization of microorganisms, evaluating decontamination methods, determining pathogenicity and virulence of infectious agents, determining the natural history of infectious organisms, and conducting epidemiologic studies and surveillance for diseases. Biodefense activities include those with select agents.
   The select agents list is available at:
   http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html

   Additional information can be found at:
   http://emergency.cdc.gov/labissues/
   http://www.cdc.gov/fmo/topic/Budget%20Information/CIO_Overviews/cio_overviews_pdf/CCID.pdf
   http://www.federallabs.org/labs/profile/?Agency=26&id=1884

Form A, Part 1

Exchange of data on research centres and laboratories[1]

1. **Name(s) of facility[2]**

   NIH, Integrated Research Facility (IRF) - Rocky Mountain Laboratories (RML)

   Declared in accordance with Form A, Part 2 (iii)

2. **Responsible public or private organization or company.**

   National Institutes of Health
   U.S. Department of Health and Human Services

3. **Location and postal address.**

   903 South 4th Street
   Hamilton, Montana 59840
   United States

4. **Source(s) of financing of the reported activity, including indication if the activity is wholly or partly financed by the Ministry of Defence.**

   U.S. Department of Health and Human Services (HHS)

5. **Number of maximum containment units[3] within the research center and/or laboratory, with an indication of their respective size (m^2).**

   BSL 4 Laboratory 631 m^2 Total

6. **If no maximum containment unit, indicate highest level of protection.**

   Not applicable.

7. **Scope and general description of activities, including type(s) of microorganisms and/or toxins as appropriate.**

   Research activities involving viruses, bacteria, rickettsiae, and prions revolve around pathogenesis studies, vaccinology, and development of therapeutic agents and rapid

[1] The containment units which are fixed patient treatment modules, integrated with laboratories, should be identified separately.
[2] For facilities with maximum containment units participating in the national biological defence research and development programme, please fill in name of facility and mark "Declared in accordance with Form A, part 2 (iii)".
[3] In accordance with the 1983 WHO Laboratory Biosafety Manual, or equivalent.

diagnostic assays in support of the civilian biodefense program.

Additional information can be found at:
http://www.niaid.nih.gov/about/organization/dir/rml/pages/default.aspx
http://www.niaid.nih.gov/about/organization/dir/rml/pages/overview.aspx

Form A - Part 2

BWC - Confidence Building Measure

Exchanges of information on national biological defence research and development programmes

United States of America

April 15, 2011

Form A, Part 2(i)

BWC - Confidence Building Measure

National biological defence research and development programme - Declaration

United States of America

April 15, 2011

Form A, Part 2 (i)

National biological defence research and development programme declaration:

I. Declaration

Is there a national programme to conduct biological defence research and development within the territory of the State Party, under its jurisdiction or control anywhere? Activities of such a programme would include prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research?

Yes	X
No	

If the answer is yes, complete Form A, part 2 (ii) which will provide a description of the programme.

Form A, Part 2(ii)

BWC - Confidence Building Measure

National biological defence research and development programme - Description

United States of America

April 15, 2011

National biological defence research and development programme

II. Description

The United States Government conducts a broad effort to reduce the risks presented by the deliberate or accidental release of biological agents and to defend against those threats in the event they occur. As called for by the National Strategy for Countering Biological Threats, this encompasses a range of initiatives, including improving global access to the life sciences to combat infectious disease regardless of its cause; establishing and reinforcing norms of safe and responsible conduct within the life sciences; improving capacity to detect and respond to outbreaks as they occur; and instituting a suite of coordinated activities that collectively help to influence, identify, inhibit, and/or interdict those who seek to misuse the life sciences.

One key element of this effort is the U.S. biodefense enterprise, which itself includes a variety of research and development programs aimed at protecting against the deliberate use of biological materials to cause harm. These programs focus on the identification of harmful pathogens and outbreaks of infectious diseases and their containment, treatment, and elimination from the environment. This biodefense enterprise is managed by several agencies with direct stakes in national security, environmental protection, and human and animal health and safety, including the Departments of Agriculture, Defense, Energy, Health and Human Services, Homeland Security, and the Environmental Protection Agency.

Historically, certain pathogens were selected for use as biological weapons because of the harm they cause in nature. General research on these pathogens, including study of molecular mechanics and related diagnostic, vaccine and therapeutic agent development work, not only increases U.S. biodefense preparedness, but offers inherent benefits for broader public health needs. Efforts to improve product stability, potency and ease-of-use that cut across disease targets could yield significant benefits for public health systems that cannot support existing treatments that require refrigeration, multiple doses or sophisticated diagnostic techniques. Similarly, biodefense initiatives to improve human and animal host defenses, to monitor emerging infectious diseases and drug-resistant microbes, and clean up the site of a biological weapons attack have civilian applications that benefit public health services, such as general disease surveillance and outbreak identification.

To promote the benefits gained by these programs and to ensure that the research is available across the scientific community both domestically and internationally, the United States Government encourages the publication of research funded by its biodefense programs.

For more information on U.S. Government strategies related to biodefense, including biological threat preparedness and response please consult:

- *Management of Domestic Incidents* (Homeland Security Presidential Directive-5 [HSPD-5]) and the related *National Response Framework*;
- *National Preparedness* (HSPD-8);
- *National Strategy for Defense of United States Agriculture and Food* (HSPD-9);

- *National Biodefense Strategy* (HSPD-10/National Security Presidential Directive-33 [NSPD-33]);
- *Medical Countermeasures against Weapons of Mass Destruction* (HSPD-18);
- *Public Health and Medical Preparedness* (HSPD-21); and
- *National Strategy for Countering Biological Threats.*

Web links to the Homeland Security Presidential Directives (HSPDs), issued by the President on matters pertaining to homeland security, can be found at:
http://www.dhs.gov/xabout/laws/editorial_0607.shtm

The *National Strategy for Countering Biological Threats* can be found at:
http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf

Form A, Part 2 (ii)

National biological defence research and development programme

II. Description

1. **State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

   The Biological Countermeasures program in the Science and Technology (S&T) Directorate of the Department of Homeland Security (DHS) is an applied research and development program that focuses emerging science and technology to provide the understanding, technologies, and systems needed to protect against biological attacks on the U.S. population, agriculture or infrastructure. The program focuses on research, development, testing, and evaluation (RDT&E) and on the transition to deployment of the needed technologies and systems. The five main areas of study are: 1) systems studies and decision support tools, 2) threat awareness, 3) surveillance and detection research and development (R&D), 4) forensics, and 5) response and restoration. The program supports other U.S. federal agencies in overall coordination of national biodefense efforts.

   Programs conducted during 2010 include systems studies and decision tools, risk assessments, biodefense knowledge management, biological warning and detection systems for critical infrastructure and urban areas, decontamination of transit systems, national bioforensic analysis; at the National Biodefense Analysis and Countermeasures Center (NBACC), biological threat characterization, development of response plans and risk communication; and at the Plum Island Animal Disease Center, development of vaccines and diagnostics for foreign animal diseases.

   The DHS Compliance Review Group, chaired by DHS Deputy Secretary, reviews all DHS-funded biological defense projects for compliance with the provisions of the Biological Weapons Convention and associated U.S. domestic laws and policies.

2. **State the total funding for the programme and its source.**

   $127,000,000 U.S. Department of Homeland Security (DHS)

3. **Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

   Yes

4. **If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

100 %

5. **Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

The Biological Countermeasures program utilizes multiple activities to carry out its mission. In the systems studies and decision tool area, research includes conducting system studies and net assessments that are used to identify effective measures for deterrence, detection, and mitigation of biological terrorism acts against the U.S. population and infrastructure.

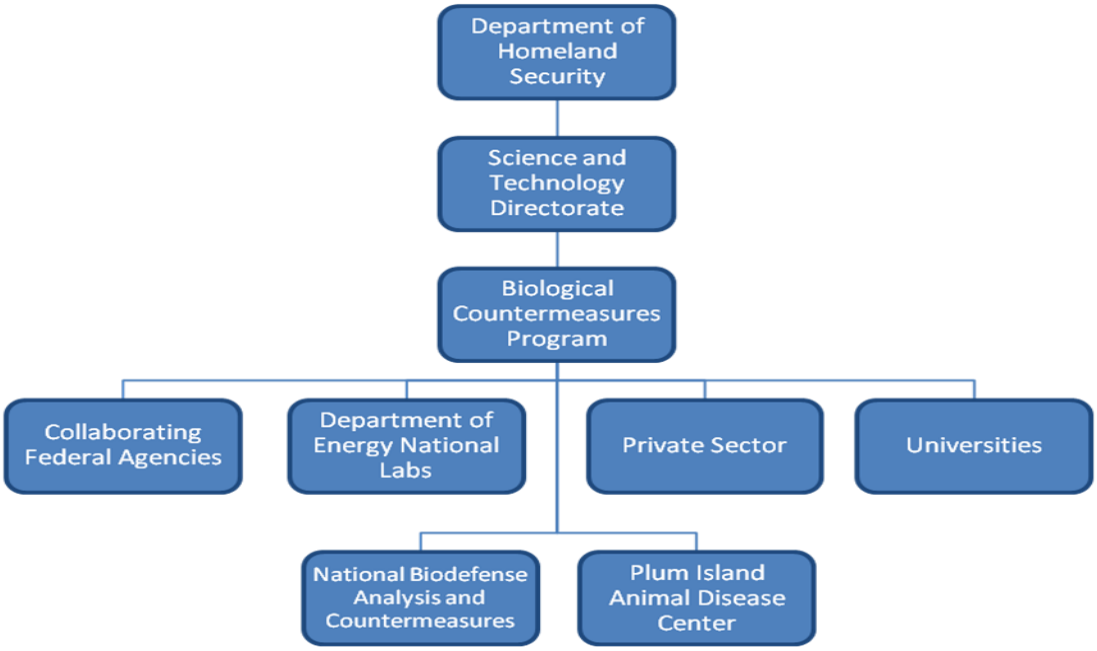
For threat awareness, efforts are underway to characterize threats posed by biological weapons, anticipate future threats, and conduct comprehensive threat and risk assessments to guide prioritization of the Nation's biodefense investments. One such ongoing effort, Project Bioshield, seeks to develop modern, effective medical countermeasures to protect the population against attack by chemical, biological, radiological, or nuclear weapons.

Within the area of surveillance and detection R&D, performers are developing next-generation detectors for biological threat agents, including fully autonomous detection capabilities for the third generation (Gen 3) BioWatch system. In addition, other efforts are underway to develop the assays (i.e., signatures or fingerprints of biological agents) needed by detectors to accurately recognize a biological agent. Another focus is on developing detect-to-protect systems specifically for use indoors as well as detection systems for protecting food products.

Under forensics, funding is devoted to operate the National BioForensics and Analysis Center (NBFAC) and conduct bioforensics research in support of criminal investigations and attribution by the appropriate Federal agency. These activities provide facilities, tools (i.e., assays, protocols, and strain libraries), analyses, and rigorous chain-of-custody controls needed to support the FBI and others in their investigation of potential biocrimes or acts of bioterrorism.

Lastly, the Biological Countermeasures program has a response and restoration element that provides advanced planning, develops concepts-of-operation, and funds exercises and training for responding to and recovering from large-scale biological attacks. Biological agents have the potential to contaminate large portions of a city, covering multiple city blocks and facilities therein. The objective is to provide a more rapid and less expensive post-attack cleanup and restoration in such situations. This program is developing a systems approach for the restoration of citywide areas and of critical facilities, such as major transportation hubs; it is not developing specific decontamination technologies. Restoration demonstrations, which bring together Federal, State, and local partners to develop, test, and then share the concepts-of-operations for key scenarios, are at the heart of this approach.

6. **Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**



7. **Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

   In accordance with Form A Part 2(iii):
   - National Biodefense Analysis and Countermeasures Center (NBACC)
   - Plum Island Animal Disease Center (PIADC)

Form A, Part 2 (ii)

National biological defence research and development programme

II. Description

1. **State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

   The Accelerated Manufacture of Pharmaceuticals (AMP) Program is creating a U.S.-based vaccine and antibody manufacturing platform capable of producing one thousand doses of vaccines or monoclonal antibodies (mAb) within 12 weeks. AMP produces life-saving vaccines and antidotes such as monoclonal antibodies (mAbs) when the pathogen itself is not available. AMP is designed to address key shortfalls in current vaccine manufacturing.

2. **State the total funding for the programme and its source.**

   $71,000,000 U.S. Department of Defense (DOD)

3. **Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

   Yes

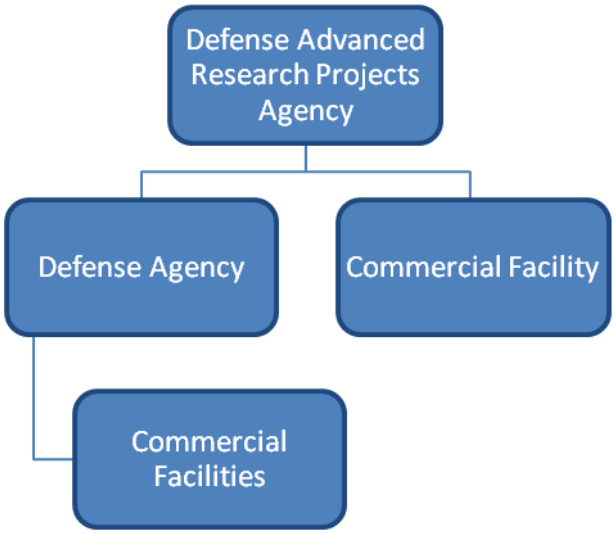
4. **If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

   100 %

5. **Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

   The AMP program seeks to produce bulk doses of vaccine quality recombinant protein and monoclonal therapies "on demand," and in large quantities against established and new biological threats. The goal of the program is to create an extremely rapid, flexible, and cost-effective production system capable of producing one thousand doses of vaccines or monoclonal antibodies (mAB) within 12 weeks.

6. **Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**



7. **Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

   Not Applicable

Form A, Part 2 (ii)

National biological defence research and development programme

II. Description

1. **State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

   The purpose of the Threat Agent Cloud Tactical Intercept and Countermeasure (TACTIC) Program is to provide the U.S. military with the capability to identify and effectively defeat/neutralize a biological threat agent cloud on the battlefield.

2. **State the total funding for the programme and its source.**

   $26,200,000 U.S. Department of Defense (DOD)

3. **Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

   Yes

4. **If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

   100 %

5. **Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

   Provide independent testing and evaluation of a countermeasure solution against a biological warfare agent simulant. The research area for this work is decontamination.

6. **Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**

7. **Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

   In accordance with Form A part 2 (iii):

   - U.S. Army Edgewood Chemical and Biological Center (ECBC)

Form A, Part 2 (ii)

National biological defence research and development programme

II. Description

1. **State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

   Joint Biological Point Detection System. Produce and field a fully automated system for point sampling, detecting, and identifying biological agents in an aerosolized environment.

   Joint Biological Tactical Detection System. Develop, produce and field a man-portable family of systems for point sampling, detecting, and identifying biological agents in an aerosolized environment.

   Joint Biological Stand-off Detection System. Develop, produce and field a system for detecting biological agent clouds at certain stand-off distances.

2. **State the total funding for the programme and its source.**

   $75,022,000 U.S. Department of Defense (DOD)

3. **Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

   Yes

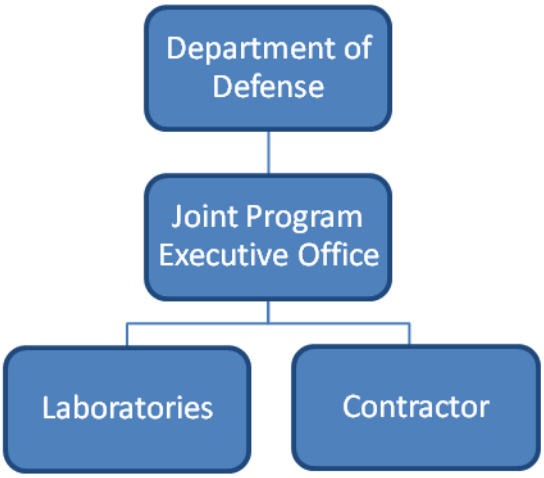
4. **If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

   70 %

5. **Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

   1) Produce components and systems
   2) Develop and test new sensor hardware and software components
   3) Develop system test methods

6. **Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**



7. **Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

   Not Applicable

Form A, Part 2 (ii)

National biological defence research and development programme

II. Description

1. **State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

   The program objective is to identify or prepare and characterize "reactive materials" to produce self-disinfecting and/or self-decontaminating materials for incorporation into protective gear and other materiel in order to provide personnel and equipment protection against both environmental and weaponized pathogens.

2. **State the total funding for the programme and its source.**

   $750,000 U.S. Department of Defense (DOD)
   $3,650,000 Other Governmental Agencies

3. **Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

   Yes

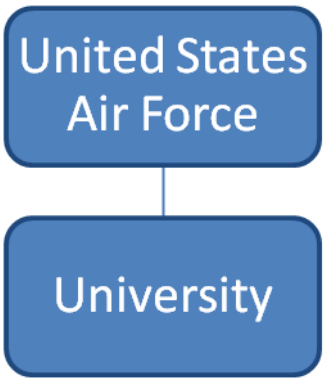
4. **If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

   60 %

5. **Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

   To classify the particle size distribution of bioaerosols, building precision aerosol deposition devices and studying post-capture fate of iodine on bioaerosol particles.

6. **Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**



7. **Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

   Not Applicable

Form A, Part 2 (ii)

National biological defence research and development programme

II. Description

1. **State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

   Decontamination Family of Systems (DFoS) will develop a Family of Systems to include equipment to improve decontamination processes, and decontaminant solutions, to meet the capability gaps for decontaminating chemical and biological warfare agents from personnel, equipment, vehicle interiors/exteriors, terrain, and fixed facilities.

2. **State the total funding for the programme and its source.**

   $2,330,000 U.S. Department of Defense (DOD)

3. **Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

   Yes

4. **If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

   100 %

5. **Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

   Facilitates the rapid transition of mature science and technology (S&T) research developments to existing Joint Project Manager Decontamination (JPM-Decon) Programs of Record and guide S&T community efforts toward meeting the needs of the warfighter.

6. **Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**

7. **Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

   Not Applicable

Form A, Part 2 (ii)

National biological defence research and development programme

II. Description

1. **State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

   The Rapid Vaccine Assessment (RVA) Program developed an Artificial Immune System (AIS) that will serve as an *in vitro* test platform to accurately test the human response to vaccines. The AIS reproduces human immune responses to experimental vaccines and drugs using a low-cost, high-throughput automated system. The platform is fully developed, capable of testing a number of vaccines against large numbers of human cells.

2. **State the total funding for the programme and its source.**

   $74,900,000 U.S. Department of Defense (DOD)

3. **Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

   Yes

4. **If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

   100 %

5. **Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

   Vaccination Site

   - Antigen presentation by dendritic cell
   - Innate response profile of vaccines
   - Immunosuppressant evaluation
   - Innate response to biologics

   Lymphoid Tissue Equivalent

   - Antigen-specific cell responses

- Responses to naïve and recall antigens
- Human primary antibody response - sub-class switching

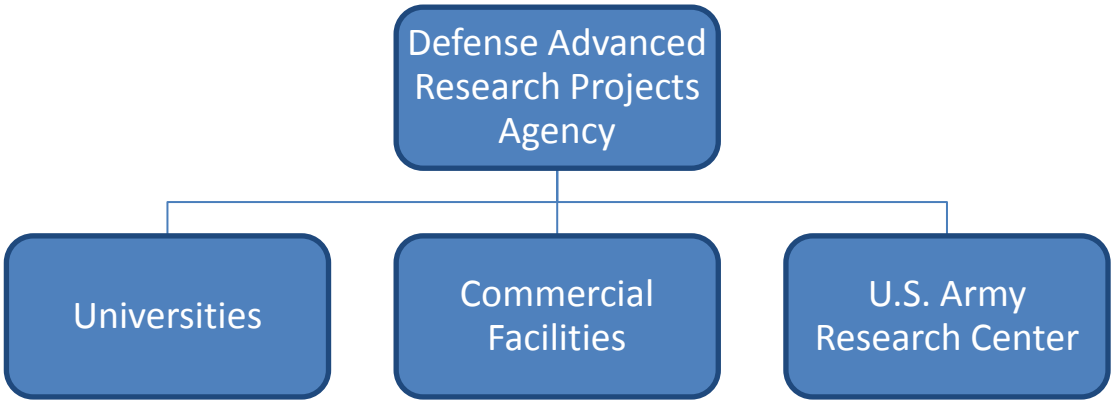
Artificial Immune System

- Developing cell response detection system
- Novel rapid microneutralization assays for membrane fusion and endocytosis viral entry

Optimization of high thru-put (HTP) testing

- Integration of robotic controls
- Confirmation of consistent results
- Automation of blood processing, vaccination site, development provides approximately 4X savings in time
- Second core automation system brought to aid in system analysis

6. Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)



7. Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.

Not Applicable

National biological defence research and development programme

II. Description

1. **State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

   The Environmental Protection Agency (EPA)'s mission is to protect public health and the environment. The National Homeland Security Research Center (NHSRC), part of the EPA's Office of Research and Development, conducts and reports on research to improve capacity to respond to and recover from environmental contamination of water infrastructure, buildings and outdoor areas by chemical, biological, radiological and nuclear (CBRN) agents. The NHSRC biodefense program focuses on EPA's two biodefense responsibilities: 1) assistance in the protection of the American water supply, and 2) decontamination of indoor and outdoor areas should the U.S. suffer a contamination incident.

   EPA is designated as the government's lead sector-specific agency for water, and is responsible for protecting water systems and detecting and recovering from terrorist attacks affecting them. EPA's homeland security research is responsible for developing products and providing expertise to protect, detect, respond to, and recover from terrorist attacks on the nation's water and wastewater infrastructure.

   EPA is also the lead federal agency for the remediation of areas contaminated by terrorist events involving the release of biological organisms, biotoxins, chemical warfare agents, toxic industrial chemicals, toxic industrial materials, and radiological materials. Terrorist acts may involve biological, chemical, and radiological agents not previously encountered as environmental pollutants. EPA's homeland security research is responsible for providing procedures and methods that will assist EPA's responders in the detection and containment of contamination, and in the remediation of sites following terrorist attacks.

2. **State the total funding for the programme and its source.**

   $8,340,000 U.S. Environmental Protection Agency (EPA)

3. **Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

   Yes

4. **If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

31 %

5. **Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

   NHSRC has research being conducted by contractors to assess risks of biological agents. Exposure studies are being conducted to estimate doses that result in adverse health effects from biological hazards. To address the need for remediating contaminated sites, NHSRC has been evaluating as well as developing analytical methods for biological agents.

6. **Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**

7. **Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

   Not Applicable

National biological defence research and development programme

Overview of HHS Biodefense Programs and Activities

Improving our nation's defenses against biological threats is a key part of the U.S. Government's homeland security effort. The U.S. Department of Health and Human Services (HHS) supports activities to improve local and state public health systems, to expand existing biosurveillance efforts, and to fund research on medical countermeasures against potential bioterror agents. HHS also has a key role in implementing the Biological Weapons Convention (BWC) tenets and the United Nations Security Council Resolution 1540 (UNSCR 1540) through a legal, extant, regulatory, and policy framework on biological risk management, and effective oversight of its biodefense programs. Many different divisions within HHS have a role in these diverse activities.

The main operating divisions of HHS involved in biodefense are: CDC (Centers for Disease Control and Prevention), NIH (National Institutes of Health), and FDA (Food and Drug Administration). The staff divisions primarily involved in biodefense issues are the Assistant Secretary for Preparedness and Response (ASPR) and the Office of Global Health Affairs (OGHA). For complete list of HHS staff and operating divisions, please see: http://www.hhs.gov/open/contacts/index.html#od

Office of the Assistant Secretary for Preparedness and Response (ASPR)
(ASPR website: http://www.PHE.gov)

The Assistant Secretary for Preparedness and Response (ASPR) is HHS's principal advisor on matters related to bioterrorism and other public health emergencies. ASPR's mission is to lead the nation in preventing, responding to and recovering from the adverse health effects of public health emergencies and disasters. ASPR provides leadership in the development and implementation of policies, plans and initiatives relevant to International Health Regulations (2005) (IHR) and facilitates implementation and manages/operates the HHS Secretary's Emergency Operations Center (SOC), which is the IHR National Focal Point. ASPR serves as a Global Health Security Action Group (GHSAG) Senior Official for HHS. GHSAG implements the Global Health Security Initiative (GHSI) - an international partnership created to strengthen global health preparedness and response for the threats of biological, chemical, radiological-nuclear terrorism (CBRN) and pandemic influenza.

Within ASPR, the Office of Policy and Planning (OPP) advises HHS and ASPR leadership on policy options and strategic planning to support domestic and international public health emergency preparedness and response activities within ASPR, HHS, and the Federal Government. OPP serves as the focal point for the National Security Staff (NSS) policy coordination activities on behalf of ASPR and leads the development and implementation of an integrated ASPR approach to policy. On behalf of HHS, ASPR is supporting the U.S. Department of State in its public diplomacy demarches related to the Biological Weapons Convention (BWC), represents HHS in the U.S. delegation to the BWC, coordinates the HHS

reporting on CBMs, and it has a key role in implementing the BWC tenets through a legal, extant, regulatory, and policy framework on biological risk management, and effective oversight of its biodefense programs.

Through the Office of Policy and Planning, ASPR is developing policy and operational frameworks for the deployment and exchange of medical countermeasures and medical personnel for international public health emergencies. Simultaneously, ASPR is looking at the issues related to receiving international assistance in the case of a significant domestic disaster, addressing issues of licensure, privileging and liability. In addition, ASPR manages the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). PHEMCE is a coordinated interagency effort which is responsible for: defining and prioritizing requirements for public health emergency medical countermeasures; focusing research, development, and procurement activities on the identified requirements; and establishing deployment and use strategies for medical countermeasures in the Strategic National Stockpile.

An organizational element within the ASPR Office, the Biomedical Advanced Research and Development Authority (BARDA) provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies. BARDA manages Project BioShield, which includes the procurement and advanced development of medical countermeasures for chemical, biological, radiological, and nuclear agents, as well as the advanced development and procurement of medical countermeasures for pandemic influenza and other emerging infectious diseases that fall outside the auspices of Project BioShield. More information on BARDA is available at: http://www.phe.gov/about/barda/Pages/default.aspx

Office of Global Health Affairs (OGHA)
(OGHA website: http://www.globalhealth.gov/office/index.html)

The Office of Global Health Affairs (OGHA) in the immediate Office of the Secretary, facilitates the Department's growing role in international health and promotes cooperative health programs in other nations. OGHA also manages the health attaché program, which deploys HHS staff to U.S. missions to serve as part of the country team and represent the U.S. government to host country ministries of health, regional organizations, the World Health organization (WHO) and other international organizations. Currently, health attachés are posted to (or being selected for) U.S. missions at New Delhi, Pretoria, Geneva, Beijing, and Brasilia. The CDC country director in Bangkok also fulfills the functions of the health attaché.

The Centers for Disease Control and Prevention (CDC)

The Centers for Disease Control and Prevention's (CDC) programs provide countermeasures to be used to protect the U.S. civilian population through research and development for vaccines and therapeutic agents and rapid, agent-specific assays. The CDC also provides information and

resources for preparing for and responding to public health emergencies. Additional information is available at: http://emergency.cdc.gov/.

CDC's strategic plan for biodefense is based on the following five focus areas, with each area integrating training and research:

- preparedness and prevention;
- detection and surveillance;
- diagnosis and characterization of biological and chemical agents;
- response; and
- communication.

In 2007, Homeland Security Presidential Directive 21 (HSPD-21) was issued in recognition of the emergence of significant health-related threats to the nation. HSPD-21 called for the development of a nationwide approach to biosurveillance in order to enhance the United States' ability to detect and respond to those threats. The Department of Health and Human Services (HHS) was charged with the responsibility of enhancing biosurveillance for human health and delegated this responsibility to CDC. Drafted with significant input from Federal, state, local, tribal, and private stakeholders, the National Biosurveillance Startegy for Human Health *(NBSHH)* was released in February 2010. The *NBSHH* established priorities for the nation's next-generation biosurveillance capability to provide timely, comprehensive, and accessible information to strengthen public health practice, provide value to clinicians, and build upon current systems and resources. Additional information on NBSHH is available at: http://www.cdc.gov/osels/pdf/NBSHH_v2.pdf

The Concept Plan for Implementation of the National Biosurveillance Strategy for Human Health was released in January 2010. The *Concept Plan* addresses three broad areas: a governance structure across the biosurveillance enterprise; the development of a registry of biosurveillance systems, programs, tools, collaboratives, and registries; and the need for a communications strategy. Additional information on the *Concept plan* is available at: http://www.cdc.gov/osels/pdf/NBSHH_v2.pdf

CDC is also the lead agency for the HHS Select Agents Program. The registration of facilities and personnel possessing, using and transferring these agents or toxins is part of the government's efforts to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies and is required under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. For more information about the Select Agents Program, please see the website of the National Select Agent Registry at: http://www.selectagents.gov

Within the Office of Infectious Disease (OID), the national center for Emerging and Zoonotic Infectious Diseases (NCEZID) and the National Center for Immunization and Respiratory Diseases (NCIRD), located in Atlanta, Georgia, conduct a variety of activities, including diagnostic techniques, assay development, molecular and antigenic characterization of microorganisms, evaluation of decontamination methods, pathogenicity, virulence, natural history, and vaccine development for select agents.

The select agents list is available at:
http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html

Within NCEZID, the Division of Vector-borne Diseases (DVBD), located in Fort Collins, Colorado, focuses on development and implementation of epidemiology and surveillance, prevention and control and improved diagnostics for diagnosis, detection and characterization of several vector-borne pathogens including various bacteria and alphaviruses, as well as serving as the national reference laboratory for these pathogens.

In addition, as a part of the CDC's National Center for Environmental Health, the Mass Spectrometry Toxin Laboratory is developing toxin assays that are critical for the public health response to biological toxins. The laboratory uses advanced mass spectrometry techniques to measure peptides and proteins that are in the pathogenic pathway of the infectious agent or toxin and uses these measurements to identify and track infection or poisoning.

The Food and Drug Administration (FDA)

The U.S. Food and Drug Administration (FDA) leads U.S. Government efforts to ensure access to safe and effective human and veterinary drugs, biological products (including allergenics, blood products, cell therapy, plasma derivatives, tissue engineering and vaccines), medical and radiation-emitting devices, cosmetics, and a safe and nutritious food supply. As a part of this mission, the FDA works with other Government agencies and private sector organizations to help reduce the risk of tampering or other malicious, criminal, or terrorist actions on the food and cosmetic supply. More information is available at:
http://www.fda.gov/Food/FoodDefense/default.htm
and
http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048251.htm

The National Institutes of Health (NIH)

The NIH, specifically the National Institute of Allergy and Infectious Diseases (NIAID), has the primary responsibility within the United States Government for civilian biodefense research. NIAID conducts and supports much of the research aimed at developing new and improved medical countermeasures against potential bioterrorism agents. The NIH/NIAID Strategic Plan for Biodefense Research is available online at:
http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Documents/biosp2007.pdf. More information is also available at:
http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Pages/default.aspx

NIAID labs involved in biodefense research include the Dale and Betty Bumpers Vaccine Research Center, IRF-Rocky Mountain Laboratories, and the C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases.

In addition, the NIAID Regional Centers of Excellence for Biodefense and Emerging Infectious Diseases (RCEs) support research focused on countering threats from bioterror agents and emerging infectious diseases. Each Center is comprised of a consortium of universities and

research institutions serving a specific geographical region. The Centers, located throughout the United States, will build and maintain a strong scientific infrastructure supporting multifaceted research and development activities that promote scientific discovery and translational research capacity required to create the next generation of therapeutics, vaccines, and diagnostics.

NIAID has set research priorities and goals for each microorganism that might be used as an agent of bioterrorism, with particular emphasis on "Category A" agents-those considered by the Centers for Disease Control and Prevention to be the most serious bioterror threats. NIAID's research agenda and strategic plan cover the following categories:

- Basic biology: understanding how microorganisms and/or their toxic products function and cause disease.
- Immunology and host response: understanding how the human immune system interacts with and defends the body against potential agents of bioterrorism.
- Vaccines: working closely with industry to create new and improved vaccines.
- Drugs: working closely with industry to develop and test drugs to treat diseases that may result from a biological attack.
- Diagnostics: developing devices or methods to quickly and accurately diagnose diseases caused by bioterrorism agents.
- Research resources: establishing biosafety laboratories, databases, and other resources to help scientists conduct safe and effective biodefense research.

Additional information is available at:
http://www.niaid.nih.gov/labsandresources/resources/rce/Pages/default.aspx.

National biological defence research and development programme

II. Description

1. **State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

   Improving our nation's defenses against bioterrorism is a key part of the U.S. Government's homeland security effort. The Department of Health and Human Services (HHS) supports activities to improve local and state public health systems, to expand existing biosurveillance efforts, and to fund research on medical countermeasures against potential bioterror agents.

   The National Institues of Health (NIH) biodefense program is supported by funding from the U.S. Department of Health and Human Services. The NIH, and specifically the National Institute of Allergy and Infectious Diseases (NIAID), has the primary responsibility within the U.S. Government for civilian biodefense research. The intent of the program is to provide countermeasures to be used to protect the U.S. civilian population through the development of vaccines, therapeutic agents and rapid, agent-specific assays.

2. **State the total funding for the programme and its source.**

   $65,497,993 U.S. Department of Health and Human Services (HHS)

3. **Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

   No

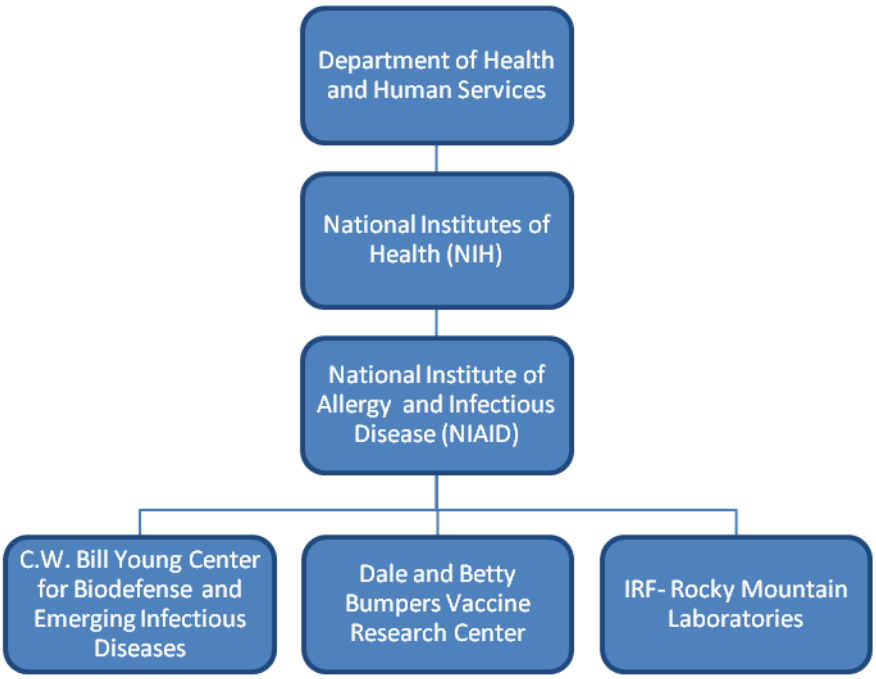
4. **If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

   Not Applicable

5. **Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

   Not Applicable

6. **Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**



7. **Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

   In accordance with Form A part 2 (iii):
   - NIH, C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases
   - NIH, Dale and Betty Bumpers Vaccine Research Center
   - NIH, Integrated Research Facility (IRF) - Rocky Mountain Laboratories (RML)

Form A, Part 2 (ii)

National biological defence research and development programme

II. Description

1. **State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

   The CDC Mass Spectrometry Toxin Laboratory has successfully developed toxin assays that are critical for better detection and diagnosis during a public health response to biological toxins. The laboratory uses advanced mass spectrometry techniques to measure peptides and proteins that are in the pathogenic pathway of the infectious agent or toxin and uses these measurements to identify and track infection or poisoning.

2. **State the total funding for the programme and its source.**

   $1,900,000 Centers for Disease Control and Prevention (CDC)

3. **Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

   Yes

4. **If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

   2 %

5. **Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

   Manufacture of botulinum neurotoxin antibodies for use in detection assays.

6. **Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**

7. **Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

   In accordance with Form A part 2 (iii):
   - CDC Mass Spectrometry Toxin Laboratory

Form A, Part 2 (ii)

National biological defence research and development programme

II. Description

1. **State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

   The activities of the CDC Office of Infectious Disease (OID) include developing diagnostic assays for public health, conducting molecular and antigenic characterization of microorganisms, evaluating decontamination methods, determining pathogenicity and virulence of infectious agents, determining the natural history of infectious organisms, and conducting epidemiologic studies and surveillance for diseases. Biodefense activities include those with select agents. OID includes the National Center for Emerging and Vector-borne Diseases (NCEZID) and the National Center for Immunization and Respiratory Diseases (NCIRD).

   The select agents list is available at:
   http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html

2. **State the total funding for the programme and its source.**

   $93,476,605 U.S. Department of Health and Human Services (HHS)

3. **Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

   Yes

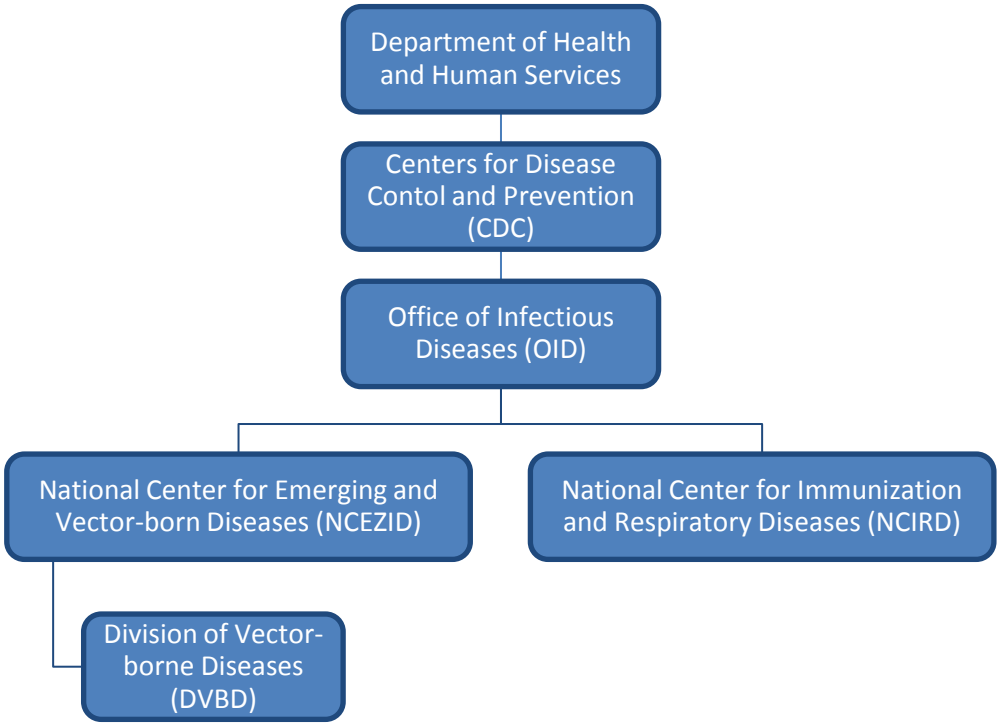
4. **If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

   5 %

5. **Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

   Vaccine efficacy trials, reagent development, bioterrorism preparedness and response activities, avian influenza preparedness, and disease surveillance in CDC field locations.

6. **Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**



7. **Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

In accordance with Form A part 2 (iii):

- CDC, NCEZID, Division of Vector Borne Diseases (DVBD)
- CDC, Office of Infectious Diseases (OID)

Form A, Part 2 (ii)

National biological defence research and development programme

II. Description

1. **State the objectives and funding of the programme and summarize the principal research and development activities conducted in the programme. Areas to be addressed shall include: prophylaxis, studies on pathogenicity and virulence, diagnostic techniques, aerobiology, detection, treatment, toxicology, physical protection, decontamination and other related research.**

   U.S. Department of Agriculture (USDA)

   Background

   Foreign animal diseases represent a major threat to U.S. agriculture. Introduction of these agents, either accidental or deliberate, has devastating social and economic effects not only in the country's agricultural systems but also in a wide range of economic activities. Diseases of concern include but are not limited to Foot-and-Mouth Disease, Avian Influenza, Rift Valley Fever, Classical Swine Fever, African Swine Fever, Exotic Newcastle disease, Vesicular stomatitis, and Exotic Bluetongue.

   Animal health officials define an exotic or foreign animal disease (FAD) as an important transmissible livestock or poultry disease believed to be absent from the U.S. and its territories that has a potential significant health or economic impact. Foreign animal diseases are considered a threat to the U.S. when they significantly affect human health or animal production and when there is an appreciable cost associated with disease control and eradication efforts. To protect the long-term health and profitability of U.S. animal agriculture, incursions of a FAD must be rapidly controlled.

   In the U.S., control usually means disease eradication. Disease eradication is currently accomplished by eliminating the animal, resulting in loss of protein, loss of income to the farm community, public opposition and environmental disruption. In addition to control costs, one of the most immediate and severe consequences of a FAD occurrence in the U.S. will be the loss of export markets. Many new issues and factors are affecting FAD prevention, control, management, and recovery. These factors include free trade agreements, free trade blocks, regionalization, increased international passenger travel, intensification of animal production, the constant evolution of infectious agents, and the uncertain impact of biotechnology and bioterrorism.

   Current methods for prevention and control of high consequence diseases, including prevention, detection, control and eradication, are not socially or economically acceptable. Rapid detection and characterization tools for prevention, control and eradication of foreign animal diseases are

inadequate or not currently available. Our understanding of pathogenesis, transmission, and immune response is insufficient to rapidly control and eradicate foreign animal diseases. Effective measures to prevent, control and eradicate foreign animal diseases are lacking or inadequate.

Strategic Objectives

- Establish Agriculture Research Service (ARS) laboratories into a fluid, highly effective research network, to maximize use of core competencies and resources.
- Access to specialized high containment facilities to study zoonotic and emerging diseases.
- Develop an integrated animal and microbial genomics research program.
- Establish centers of excellence in animal immunology.
- Launch a biotherapeutic discovery program providing alternatives to animal drugs.
- Build a technology-driven vaccine and diagnostic discovery research program.
- Develop core competencies in field epidemiology and predictive biology.
- Develop internationally recognized OIE expert collaborative research laboratories.
- Establish best in class training center for our nation's veterinarians and scientists.
- Develop a model technology transfer program to achieve the full impact of our research discoveries.

Research Needs

In order to control foreign animal disease, a wide variety of agent detection platforms need to be developed and validated. Information for design of these platforms will come in part from further knowledge of pathogen genomics and proteomics and in part from understanding the evolution and genetic variability of disease agents. Although many of the foreign animal diseases have existed for many years in other countries, more fundamental knowledge of these agents is required. There is still a lack of understanding in host range and tissue tropism, carrier state, duration and routes of shedding, transmission mechanisms, (e.g., vectors, fomites, aerosols), ecology and epidemiology (e.g., wildlife reservoirs). If these diseases should occur in the U.S., more effective prevention and control tools, such as identifying suitable control strategies compatible with short time and cost of recovery from disease outbreaks (DIVA compatible), need to be developed. There is a need for development of vaccines and biotherapeutics suitable for strategic stockpiles and integrated methods of disease control, including vector control and animal management, which all lead to a better capability to regain country disease-free status and retain economic sustainability.

Expected Outputs:

- Better anticipation of introduction of foreign animal diseases.
- Capability to advise regulatory officials on scientific procedures for the prevention of introduction of FADs.
- Better capability to produce effective products to control and eliminate foreign animal

diseases.

- Real-time detection of agents in a wide range of farm matrices.
- Searchable databases of genome and proteome information for major known FAD agents.
- Improved ability to predict or anticipate emergence or introduction of FAD agents.
- Discovery of effective candidate biotherapeutics.
- Discovery of effective candidate vaccines that allow differentiation of infected animals from vaccinated animals (DIVA).
- Viable integrated vector control strategies that minimize losses.

The USDA-ARS biodefense research program is intramural and implemented in ARS high containment facilities in the following locations: Ames, Iowa; Orient Point, New York; Athens, Georgia; Frederick, Maryland.

2. **State the total funding for the programme and its source.**

   $20,435,000 U.S. Department of Agriculture (USDA)

3. **Are aspects of the programme conducted under contract with industry, academic institutions, or in other non-defence facilities?**

   No

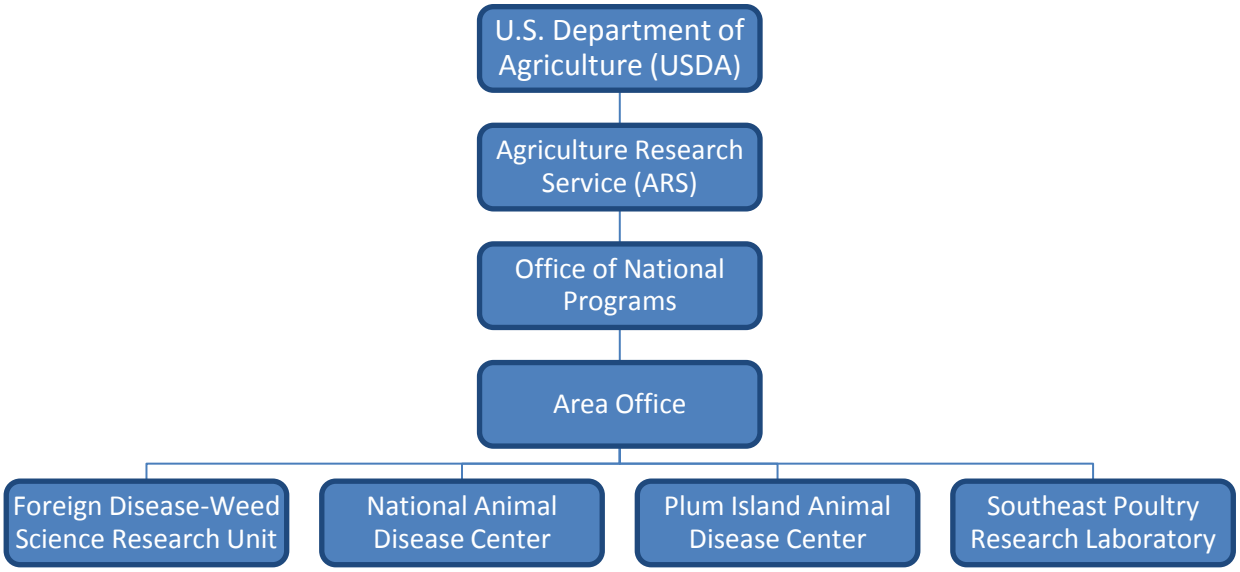
4. **If yes, what proportion of the total funds for the programme is expended in these contracted or other facilities?**

   Not Applicable

5. **Summarize the objectives and research areas of the programme performed by contractors and in other facilities with the funds identified in paragraph 4.**

   Not Applicable

6. **Provide a diagram of the organizational structure of the programme and the reporting relationships (include individual facilities participating in this programme.)**



7. **Provide a declaration in accordance with Form A part 2 (iii) for each facility, both governmental and non-governmental, which has a substantial proportion of its resources devoted to the national biological defence research programme, within the territory of the reporting State, or under its jurisdiction or control anywhere.**

   In accordance with Form A part 2(iii):
   - Foreign Disease-Weed Science Research Unit
   - National Animal Disease Center (NADC)
   - Plum Island Animal Disease Center (PIADC)
   - Southeast Poultry Research Laboratory

Form A, Part 2(iii)

BWC - Confidence Building Measure

National biological defence research and development programme - Facilities

United States of America

April 15, 2011

Form A, Part 2 (iii)

National biological defence research and development programme

The U.S. Government identified potential concerns associated with public release of information on the identity of biological agents at specific facilities.

To balance these concerns with a desire to promote transparency, in Form A Part 2(iii) the U.S. submission characterizes the agents used for biological defense research at each facility by identifying:

- whether there are **Biological Select Agent and Toxins** (Select Agent) present at the facility, and if so, which subcategories (HHS, Overlap, USDA, and USDA PPQ) are represented;
- for each Select Agent subcategory, whether these agents are also listed under **NIAID Category A, B, or C Priority Pathogens;**
- whether there are non-Select Agent **NIAID Category A, B or C Priority Pathogens** present at the facility; and
- other relevant information as appropriate.

Biological Select Agents and Toxins (Select Agents) are biological agents or toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products, whose possession, use and transfer are regulated by the Select Agent Rules. Additional information on Select Agents can be found at:
http://www.selectagents.gov

The **NIAID list of Category A, B and C Priority Pathogens** identifies specific pathogens as priorities for additional research efforts as part of the NIAID biodefense research agenda. Additional information on NIAID Category A, B and C Priority Pathogens can be found at:
http://funding.niaid.nih.gov/ncn/glossary/default5.htm
http://pathema.jcvi.org/pathema/AbcGenomes.shtml
http://www.fas.org/irp/threat/cbw/niaid0803.pdf
http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Documents/categorybandc.pdf

Using the two lists to categorize the agents at a facility offers greater transparency into the types of agents than using either list alone. Lists of **Biological Select Agents and Toxins**, and **NIAID Category A, B, C Priority Pathogens** can be found in Appendix A of the CBM submission (pages 285-289). A compiled list of microorganisms and toxins used for biological defense research at the facilities reported in Form A Part 2(iii) can be found in Appendix B of the CBM submission (pages 290-296).

To maintain our existing high level of transparency to States Parties, we are making available, to all States Parties, information on agents consistent with previous submissions.

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

National Biodefense Analysis and Countermeasures Center (NBACC)

2. Where is it located (provide both address and geographical location)?

8300 Research Plaza
Fort Detrick, Maryland 21702

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	1032
BL3 (sqM)	3160
BL4 (sqM)	976
Total (sqM)	5168

4. The organizational structure of each facility.

I Total Number of Personnel 167

II Division of Personnel:

Military	0
Civilian	167

III Division of Personnel by Category:

Scientists	34
Engineers	16
Technicians	73
Administrative/Support	44

IV List the scientific disciplines represented in the scientific/engineering support staff.

Bacteriology
Biochemistry
Bioinformatics
Biology
Biomedical Science
Biophysics

Biotechnology
Cell Biology
Chemistry
Computer Science
Genetics
Immunology
Molecular Biology
Molecular Pathogenic Microbiology
Pathology
Veterinary Medicine
Virology

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 167

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Homeland Security (DHS)

VII What are the funding levels for the following program areas:

Research	$11,036,000
Development	$ 8,100,000
Test and evaluation	$ 0
Total	$19,136,000

VIII Briefly describe the publication policy of the facility:

The NBACC policy is to present research results to the greater scientific community as widely as possible. As a Federally Funded Research and Development Center engaged in research with select agents/regulated pathogens, NBACC has established a formal, multi-tiered review system to ensure compliance and conformance with U.S. Government regulations including export control regulations under EAR/ITAR, the Biological Weapons Convention (BWC), and internal DHS policies. All publications are reviewed by NBACC and DHS prior to release to ensure clarity and accuracy with regard to the description of the work.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Burans, J, Ed, Budowle, B, Schutzer, S., Keim, P. and Morse, S. *"Microbial Forensics, 2nd*

Ed, National Bioforensic Analysis Center." Academic Press, Sept, 2010.

Burans, J., Fletcher, J., Barnaby, N., Nutter, F., Ochoa-Corona, F., Budowle, B., Schutzer, S., Keim, P., and Morse, S. *"Microbial Forensics, 2nd Ed, Forensic Plant Pathology."* Academic Press, Sept, 2010.

Swearengen, J. R., Vargas, K. J., Tate, M. K., and Linde, N. S. *"Disaster preparedness in biocontainment animal research facilities: developing and implementing an incident response plan (IRP)."* ILAR Journal, Institute for Laboratory Animal Research; 51:120-126; March 31, 2010.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
The NBACC mission is to provide the nation with the scientific basis for characterization of biological threats and bioforensic analysis to support attribution of their use against the American public. NBACC conducts studies to fill in information gaps to better understand current and future biological threats; to assess vulnerabilities; and to determine potential impacts to guide the development of countermeasures such as detectors, drugs, vaccines, and decontamination technologies. When needed, NBACC conducts experimental programs to better characterize the benefits and risks of changes in U.S. biodefense preparations. NBACC also develops bioforensic assays and provides operational forensic analysis to support the attribution of planned and actual events of biocrime and bioterrorism.

Laboratory research began at NBACC in November 2010 at BSL-2 containment.

II. Agents Microorganisms and/or Toxins:

- **Other pathogens or toxins**

In 2010, the NBACC was not yet registered to conduct work in house with select agents/toxins.

III. Outdoor Studies:
None

[*] Including viruses and prions.

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Plum Island Animal Disease Center (PIADC)

2. Where is it located (provide both address and geographical location)?

40550 Rte. 25
Orient Point New York 11957

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	234
BL3 (sqM)	17643
BL4 (sqM)	0
Total (sqM)	17877

4. The organizational structure of each facility.

I Total Number of Personnel 357

II Division of Personnel:

Military	0
Civilian	357

III Division of Personnel by Category:

Scientists	92
Engineers	2
Technicians	13
Administrative/Support	250

IV List the scientific disciplines represented in the scientific/engineering support staff.

Biology
Chemistry
General Engineering
Microbiology
Molecular Biology
Molecular Computational Biology

Pathology
Research facility operations
Veterinary Clinical Research
Veterinary Medicine

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 236

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Homeland Security (DHS)
U.S. Department of Agriculture (USDA)

VII What are the funding levels for the following program areas:

Research	$ 4,000,000
Development	$ 8,000,000
Test and evaluation	$ 4,000,000
Total	$16,000,000

VIII Briefly describe the publication policy of the facility:

DHS scientific research staff are expected to publish papers in open literature. Papers are peer reviewed and approved by DHS prior to submittal to journals. DHS has no official publication policy.

USDA ARS has several publication policies (website links in parenthesis):

- Policy Number 150.1 "Dissemination of Public Information by ARS" (http://www.afm.ars.usda.gov/ppweb/PDF/150-01.pdf);
- Number 113.1 "Publishing (Print and Electronic) (www.**afm.ars.usda.gov**/ppweb/2010/113-1-**ARS**.pdf); and
- Number 152.1 "Procedures for Publishing Manuscripts and Abstracts with Non-USDA Publishers (Outside Publishing) (http://www.afm.ars.usda.gov/ppweb/pdf/152-01.pdf)

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Adell, A.D., Perez A.M., Lopez, R.N., Gonzalez, I.L., Ramirez, P.P., Rodriguez, L.L.

Estimation of the time of seroconversion to the New Jersey serotype of vesicular stomatitis virus in sentinel cattle of dairy herds located at high and low elevations in southern Mexico. American Journal of Veterinary Research, December 2010, 71(12):1551-1456.

Arzt, J., White W.R., Thomsen B.V., Brown C.C. Agricultural diseases on the move early in the third millennium. Veterinary Pathology, January 2010, 47(1):15-27.

Arzt, J., Pacheco J.M., Rodriguez L.L. The early pathogenesis of Foot-and-Mouth in cattle after aerosol inoculation: identification of the Nasopharynx as the primary site of infection. Veterinary Pathology, June 30, 2010, p.1-16.

Carrillo, A.C., Thissen, J., Olivas, K., Pitz, M., Sheikh, EL., Harrel, B., Hall, S., Rassmussen, M., Tammero, L.B., Lenhoff, R., Arani, P.N. Multiplexed diagnostic assays for detection of high consequence foreign and emerging animal disease. 14th International Congress on Infectious Diseases (ICID) Abstracts.

Carrillo, C., Prarat, M., Vagnozzi, A., Calahan, J.D., Smoliga, G., Nelson, W.M., Rodriguez, R.R. Specific detection of Rinderpest Virus by real-time RT-PCR in preclinical and clinical samples of experimentally infected cattle. Journal of Clinical Microbiology: published online ahead of print: September 2010: p.11-13.

Dias, C.C.A., Moraes, M.P., Diaz-San Segundo, F., de los Santos, T., Grubman, M.J. Porcine Type I interferon rapidly protects swine against challenge with multiple serotypes of Foot-and-Mouth Disease Virus. Journal of Interferon and Cytokine Research, 2010.

Diaz-San Segundo F., Moraes M.P., de los Santos T., Dias C.C.A., Grubman M.J. Interferon-induced protection against Foot-and-Mouth Disease Virus infection correlates with enhanced tissue-specific innate immune cell infiltration and interferon-stimulated gene expression. Journal of Virology, Feb 2010, 84(4):2063-2077.

Durk, R.C., Singh, K., Cornelison, C.A., Rai, D.K., Matzek, K.B., Leslie, M.D., Schafer, E., Marchand, B., Adedeji, A., Michailidis, E., Dorst, C.A., Moran, J., Paultler, C., Rodriguez, L.L., McIntosh, M.A., Rieder, E., Sarafianos, S.G. Inhibitors of Foot and Mouth Disease Virus targeting a novel pocket of the RNA-Dependent RNA polymerase. PLoS One, December 2010, 5(12):1-14.

Fernandez-Sainz I., Gladue D.P., Holinka L.B., O'Donnell V., Gudmundsdottir I., Prarat M., Patch J.R., Golde W.T., Lu Z., Zhu J., Carrillo C., Risatti G.R., Borca M.V. Mutations in Classical Swine Fever Virus NS4B affect virulence in swine. Journal of Virology, Feb 2010, 84(3):1536-1549.

Gladue D.P., Holinka L.G., Fernandez-Sainz I.J., Prarat M.V., O'Donnell V., Vepkhvadze N., Lu Z., Rogers K., Risatti G.R., Borca M.V. Effects of the interactions of Classical Swine Fever Virus core protein with proteins of the SUMOylation pathway on virulence in swine.

Virology (2010-article in press).

Gladue D.P., Zhu J., Holinka L.G., Fernandez-Sainz I., Carrillo C., Prarat M.V., O'Donnell V., Borca M.V. Patterns of gene expression in swine macrophages infected with Classical Swine Fever Virus detected by microarray. Virus Research, July 2010, 151(1):10-18.

Grubman M.J., Moraes M.P., Schutta C., Barrera J., Neilan J., Ettyreddy D., Butman B.T., Brough D.E., Brake D.A. Adenovirus serotype 5-vectored Foot-and-Mouth Disease subunit vaccines: the first decade. Future Virology, Jan 2010, 5(1):51-64.

Grubman, M.J., Rodriguez L.L., de los Santos T. Foot-and-Mouth Disease. IN: Ehrenfeld E, Domingo E, Roos R.P., editors. The Picornavirurses, Washington, DC: ASM Press, c2010. p.397-410.

He D., Overend C., Ambrogio J., Maganti R.J., Grubman M.J., Garmendia A.E. Marked differences between MARC-145 cells and swine alveolar macrophages in IFNB-induced activation of antiviral state against PRRSV. Veterinary Immunology and Immunopathology (2010).

Jesudhasan P.R., Cepeda M.L., Widmer K., Dowd S.E., Soni K.A., Hume M.E., Zhu J., Pillai S.D. Transcriptome analysis of genes controlled by luxS/Autoinducer-2 in Salmonella enterica serovar typhimurium. Foodborne Pathogens and Disease, April 2010 7(4):399-410.

Krug P.W., Schinazi R.F., Hilliard J.K. Inhibition of B Virus (Macacine herpesvirus 1) by conventional and experimental antiviral compounds. Antimicrobial Agents and Chemotherapy, Jan 2010 54(1):452-459.

Maree F.F., Blignaut B., de Beer T.A.P., Visser N., Rieder E.A. Mapping of amino acid residues responsible for adhesion of cell culture-adapted Foot-and-Mouth Disease SAT type viruses. Virus Research, Oct 2010 153(1):82-91.

Metwally S., Mohamed F., Faaberg K., Burrage T., Prarat M., Moran K., Bracht A., Mayr G., Berninger M., Koster L., To T.L., Nguyen V.L., Reising M., Landgraf J., Cox L. Pathogenicity and molecular characterization of emerging porcine reproductive and respiratory syndrome virus in Vietnam in 2007. Transboundary and Emerging Diseases, Oct 2010 57(5):315-329.

Mohamed F., Swafford S., Petrowski H., Bracht A., Schmit B., Fabian A.,Pacheco J., Hartwig E., Berninger M., Carrillo C., Mayr G., Moran K., Kavanaugh D., Leibrecht H., White W., Metwally S. Foot-and-Mouth Disease in feral swine: susceptibility and transmission. Transboundary and Emerging Diseases, 2010.

Nfon C.K., Toka F.N., Kenney M., Pacheco J.M., Golde W.T. Loss of plasmacytoid dendritic cell function coincides with lymphopenia and viremia during Foot-and-Mouth

Disease Virus infection. Viral Immunology, Feb 2010 23(1):29-41.

Pacheco J.M., Piccone M.E., Rieder E., Pauszek S.J., Borca M.V., Rodriguez L.L. Domain disruptions of individual 3B proteins of Foot-and-Mouth Disease Virus do not alter growth in cell culture or virulence in cattle. Virology, Sept 15, 2010 405(1):149-156.

Pacheco J.M., Arzt J., Rodriguez L.L. Early events in the pathogenesis of Foot-and-Mouth Disease in cattle after controlled aerosol exposure.Veterinary Journal, Jan 2010 183(1):46-53.

Pacheco J.M., Mason P.W. Evaluation of infectivity and transmission of different Asian Foot-and-Mouth Disease viruses in swine. Journal of Veterinary Science, June 2010 11(2):133-142.

Pacheco J.M., Butler J.E., Jew J., Ferman G.S., Zhu J., Golde W.T. IgA antibody response of swine to Foot-and-Mouth Disease Virus infection and vaccination. Clinical and Vaccine Immunology, April 2010 17(4):550-558.

Patch, J.R., Pedersen, L.E., Toka, F.N., Moraes, M., Grubman, M.J., Nielsen, M., Jungersen, G., Buus, S., Golde, W.T. Induction of foot and mouth disease virus (FMDV) specific cytotoxic T cell killing by vaccination. Clinical of Vaccine Immunology: published ahead of print on December 22, 2010.

Perez A.M., Pauszek S.J., Jimenez D., Kelley W.N., Whedbee Z., Rodriguez L.L. Spatial and phylogenetic analysis of vesicular stomatitit virus over-wintering in the United States. Preventive Veterinary Medicine, March 2010 93(4):258-264.

Piccone M.E., Pacheco J.M., Pauszek S.J., Kramer E., Rieder E., Borca M.V., Rodriguez L.L. The region between the two polyprotein initiation codons of Foot-and- Mouth Disease Virus is critical for virulence in cattle. Virology, Jan 5, 2010 396(1):152-159.

Reeve, R., Blignaut, B., Esterhuysen, J.J., Opperman, P., Matthews, L., Fry, E.E., de Beer, Tjaart A.P., Theron, J., Rieder, E., Vosloo, W., O'Neill, H.G., Haydon, D.T., Maree, F.F. Sequence-based prediction for vaccine strain selection and identification of antigenic variability in foot and mouth disease virus. PLoS computational biology, December 2010, 6(12):e1001027.

Smith, P.F., Howerth, E.W., Carther, D., Gray, E.W., Noblet, R., Smoliga, G., Rodriguiz, L.L., Mead, D.G. Domestic cattle as a non-conventional amplifying host of vesicular stomatitis New Jersey virus. Medical and Veterinary Entomology, 2010.

Szczepanek S.M., Tulman E.R., Gorton T.S., Liao X., Lu Z., Zinski J., Aziz F., Frasca Jr S., Kutish G.F., Geary S.J. Comparative genomic analyses of attenuated strains of Mycoplasma gallisepticum. Infection and Immunity, April 2010 78(4):1760-1771.

Trujillo C.M., Rodriguez L., Rodas J.D., Arboleda J.J. Experimental infection of DIDELPHIS MARSUPIALIS with vesicular stomatitis New Jersey virus. Journal of Wildlife Disease, Jan 2010 46(1):209-217.

Woodland D.L. A strong start to 2010. Viral Immunology, Feb 2010 23(1):1-2.

Zhu J., Weiss M., Grubman M.J., de los Santos T. Differential gene expression in bovine cells infected with wild type and leaderless Foot-and-Mouth Disease Virus. Virology, August 15, 2010 404(1):32-40.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
PIADC provides the only research and development and confirmatory diagnostic capability for specific high-consequence, contagious, foreign animal diseases of livestock in the U.S. The focus of the research is on pathogens that infect animals, not those that infect humans. Technologies researched and developed are vaccines, antivirals and diagnostic methods. The facility also trains veterinarians to field diagnose high consequence foreign animal disease.

II. Agents Microorganisms and/or Toxins:

- **USDA Select Agents and Toxins**

The facility maintains a reference repository of animal disease agents (and diagnostic capabilities to recognize them should they occur in the U.S.)

III. Outdoor Studies:
Vaccine safety studies with non-live, non-replicating, virus-like particles were conducted on the U.S. mainland this past year. All other work was confined to BSL-2 and BSL-3 biocontainment facilities.

* Including viruses and prions.

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Battelle Biomedical Research Center

2. Where is it located (provide both address and geographical location)?

1425 State Route 142
West Jefferson Ohio 43162

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	1483
BL3 (sqM)	6549
BL4 (sqM)	0
Total (sqM)	8032

4. The organizational structure of each facility.

I Total Number of Personnel 185

II Division of Personnel:

Military	0
Civilian	185

III Division of Personnel by Category:

Scientists	49
Engineers	1
Technicians	98
Administrative/Support	37

IV List the scientific disciplines represented in the scientific/engineering support staff.

Aerobiology
Biochemistry
Biomedical Engineering
Chemistry
Microbiology
Molecular Biology

Molecular Toxicology
Pathology
Pharmacology
Statistics
Toxicology
Toxinology
Veterinary Medicine
Virology

V Are contractor staff working in the facility? If so, provide an approximate number.

No

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)
U.S. Department of Health and Human Services (HHS)
U.S. Environmental Protection Agency (EPA)
U.S. Department of Homeland Security (DHS)

VII What are the funding levels for the following program areas:

Research	$25,500,000
Development	$25,500,000
Test and evaluation	$ 1,300,000
Total	$52,300,000

VIII Briefly describe the publication policy of the facility:

Publication is based on permission from the study sponsor. Battelle has a peer review of publications prior to release.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Brown JN, Palermo RE, Baskin C, Gritsenko M, Sabourin PJ, Long JP, Sabourin CL,Jacobs JM, Smith RD, Katze MG. Macaque pulmonary response to Highly Pathogenic Avian Influenza and 1918 reassortant influenza infections. Journal of Virology, 84:12058-12068, 2010.

Clement KH, Rudge TL, Mayfield HJ, Carlton LA, Hester A, Niemuth NA, Sabourin CL, Brys AM, Quinn, CP. Vaccination of Rhesus macaques with AVA produces a serum

antibody response that effectively neutralizes receptor bound Protective Antigen in vitro. Clinical Vaccine Immunology, 17:1753-62, 2010.

Comer JE, Sturdevant DE, Carmody AB, Virtaneva K, Gardner D, Long D, Rosenke R, Porcella SF, Hinnebusch BJ. (2010) Transcriptomic and innate immune responses to *Yersinia pestis* in the lymph node during bubonic plague. Infect Immun. 78:5086-98.

Eshun FK, MA Currier, RA Gillespie, JL Fitzpatrick, WH Baird, and TP Cripe. 2010. VEGF blockade decreases the tumor uptake of systemic oncolytic herpes virus but enhances therapeutic efficacy when given after virotherapy. Gene Therapy 17: 922-929

Gainey MR, Wasko AM, Garver JN, Guistino DJ, Vela EM and JE Bigger. 2010. Development of a high-throughput cell based 384-well influenza A quantification assay for interpandemic and highly pathogenic avian strains. *Health*, (2)1:32-37.

Garver J and Vela EM. 2010. Dengue virus Pathogenesis and Animal Modeling. *Dengue Virus: Detection, Diagnosis and Control*. Nova Publishers.

Garver J., and Vela, E.M. 2010. *Dengue Virus Pathogenesis and Animal Modeling: Dengue Virus: Detection, Diagnosis and Control.* Hauppauge, NY: Nova Science Publishers.

Lukashevich IS and EM Vela. 2010. Pathogenesis of Lassa Virus Infection. *Molecular Pathogenesis of Hemorrhagic Fever Viruses.* Transworld Research Network.

Rozak DA, HC Gelhaus, M Smith, M Zadeh, L Huzella, D Waag, and JJ Adamovicz. 2010. CpG oligodeoxyribonucleotides protect mice from Burkholderia pseudomallei but not Francisella tularensis Schu S4 aerosols. *Journal of Immune Based Therapies and Vaccines*, 8(1):2.

Sanford, D., Barnewall, R.E., Vassar, M.L., Niemuth, N., Metcalfe, K., House, R.V., Henderson, I., and Shearer, J.D. 2010. Inhalational Botulism in Rhesus Macaques Exposed to Botulinum Neurotoxin Complex Serotypes A1 and B1. Clin Vaccine Immunol. 7(9):1293-304.

Tolnay AE, CR Baskin, TM Tumpey, PJ Sabourin, CL Sabourin, JP Long, JA Pyles, RA Albrecht, A GarcÄ±Â´a-Sastre, MG Katze, and H Bielefeldt-Ohmann. 2010. Extrapulmonary tissue responses in cynomolgus macaques (*Macaca fascicularis*) infected with highly pathogenic avian influenza A (H5N1) virus. Arch. Virol. 155: 905 - 914.

Vela EM, K Knostman, R Warren, J Garver, and R Stammen. 2010. The Disease Progression Associated with Pirital Virus Infection in the Syrian Golden Hamster. *Journal of Infectious Diseases and Immunity*, (2)1: 15-23.

Vela EM, K Knostmna, R Warren, J Garver and R Stammen. 2010. A General Kinase Inhibitor as a Potential Antiviral for Arenaviral Hemorrhagic Fever as Described in the

Pirital Virus-Syrian Golden Hamster Model. Antiviral Research Accepted.

Vela, EM., KA. Knostman, JM. Mott, RL. Warren, JN. Garver, LJ. Vela, and RL. Stammen. 2010. Genistein, a general kinase inhibitor, as a potential antiviral for arenaviral hemorrhagic fever as described in the Pirital virus-Syrian golden hamster model. Antiviral Res. **87**:318-328. doi:S0166-3542(10)00640-6 [pii];10.1016/j.antiviral.2010.06.007 [doi].

Vela EM, K Knostmna, R Warren, J Garver and R Stammen. 2010. The disease progression associated with Pirital virus infection in the Syrian golden hamster. Accepted Journal of Infectious Diseases

Vela EM. 2010. Introduction-The Molecular Pathogenesis caused by Hemorrhagic Fever Virus Infection. *Molecular Pathogenesis of Hemorrhagic Fever Viruses.* Transworld Research Network.

Warren, R., H. Lockman, R. Barnewall, R. Krile, O. B. Blanco, D. Vasconcelos, J. Price, R. V. House, M. A. Bolanowksi, and P. Fellows. 2011. Cynomolgus macaque model for pneumonic plague. Microb.Pathog. 50:12-22.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
Test and evaluation of medical countermeasures against biological threat/terrorism agents.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category A and B Priority Pathogens
- **Overlap Select Agents**
  Including NIAID Category A and B Priority Pathogens
- **Other pathogens or toxins**
  Including non-Select Agent, NIAID Category A and C Priority Pathogens

III. Outdoor Studies:
None

* Including viruses and prions.

Form A, Part 2 (iii)

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Lothar Salomon Test Facility (LSTF)

2. Where is it located (provide both address and geographical location)?

2029 Burns Rd
Dugway Utah 84022-5006

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	744
BL3 (sqM)	414
BL4 (sqM)	0
Total (sqM)	1158

4. The organizational structure of each facility.

I Total Number of Personnel 56

II Division of Personnel:

Military	0
Civilian	56

III Division of Personnel by Category:

Scientists	36
Engineers	1
Technicians	7
Administrative/Support	12

IV List the scientific disciplines represented in the scientific/engineering support staff.

Aerobiology
Bacteriology
Biochemistry
Engineering
Immunology
Microbiology
Molecular Biology

Toxicology
Virology

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 12

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)

VII What are the funding levels for the following program areas:

Research	$ 0
Development	$ 0
Test and evaluation	$3,770,000
Total	$3,770,000

VIIIBriefly describe the publication policy of the facility:

Professional scientists are encouraged to publish worthy papers in peer reviewed journals. All publications must obtain the necessary command permission before submission.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

None

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
Testing of battlefield detection and identification methods, protective equipment, and decontamination systems, to include interferent testing of biological detectors and to develop/validate aerosol particle dispersion models.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category A and B Priority Pathogens

* Including viruses and prions.

- **Overlap Select Agents**
  Including NIAID Category A and B Priority Pathogens
- **Other pathogens or toxins**
  Including non-Select Agent, NIAID Category B Priority Pathogens

III. Outdoor Studies:
Yes - using simulants

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Naval Medical Research Center (NMRC)

2. Where is it located (provide both address and geographical location)?

503 Robert Grant Avenue
Silver Spring Maryland 20910

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	100
BL3 (sqM)	35
BL4 (sqM)	0
Total (sqM)	135

4. The organizational structure of each facility.

I Total Number of Personnel 83

II Division of Personnel:

Military	16
Civilian	67

III Division of Personnel by Category:

Scientists	23
Engineers	0
Technicians	52
Administrative/Support	8

IV List the scientific disciplines represented in the scientific/engineering support staff.

Biochemistry
Immunology
Microbiology
Molecular Biology
Parasitology

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 62

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)

VII What are the funding levels for the following program areas:

Research	$2,644,000
Development	$ 0
Test and evaluation	$ 0
Total	$2,644,000

VIII Briefly describe the publication policy of the facility:

Professional scientists are encouraged to publish worthy papers in peer reviewed journals. All publications must obtain the necessary command permission before submission.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Chen PE, Cook C, Stewart AC, Nagarajan N, Pop M, Thomason B, Kiley MP, Lentz S, Nolan N, Sozhamannan S, Sulakvelidze A, Mateczun AJ, Du L, Zwick ME, Read TD. Genomic characterization of the Yersinia genus. Genome Biol. 2010 Jan 4;11(1):R1.

Sozhamannan S, Bishop-Lilly K, Rajavel M. Whole genome sequencing (WGS) and the changing landscape of bacterial genetics. Microbe.2010 Feb; 5(2):41-2.

Nalbantoglu U, Sayood K, Dempsey MP, Iwen PC, Francesconi SC, Barabote RD, Xie G, Brettin TS, Hinrichs SH, Fey PD. Large direct repeats flank genomic rearrangements between a new clinical isolate of Franciscella tularensis subsp. tularensis A1 and Schu S4. PLoS ONE. 2010 Feb 3; 5(2):e9007.

Pesce JT, Bachelder EM, Albrecht MT, Mateczun AJ, Beaudette TT, Frechet JMJ, Keane-Myers AM. In vitro analysis of acetalated dextran microparticles as a potent delivery platform for vaccine adjuvants. Mol Pharm 2010 Jun 7;7(3):826-35. Epub 2010 Apr 1.

Nagarajan N, Cook C, Bonaventure MPD, Ge H, Richards A, Bishop-Lilly KA, DeSalle R, Read TD, Pop M. Finishing genomes with limited resources: lessons from an ensemble of

microbial genomes. BMC Genomics. 2010 Apr 16;11(1):242.

Aikembayev A, Lukhnova L, Temiraliyeva G, Meka-Mechenko T, Pazylov Y, Zakaryan S, Denissov J, Easterday WR, Van Ert MN, Keim P, Francesconi SC, Blackburn JK, Hugh-Jones M, Hadfield TL. Historical distribution and molecular diversity of Bacillus anthracis, Kazakhstan. EmergInfectDis. 2010 May; 16(5):789-96. (Work completed prior to SCF's employment at NMRC.)

Sastalla I, Maltese L, Pomerantseva O, Pomerantsev A, Keane-Myers AM, Leppla SH. Activation of the latent PlcR regulon in Bacillus anthracis. Microbiology. 2010 Oct; 156(Pt 10): 2982-93. Epub 2010 Aug 5.

Chen PE, Willner K, Butani A, Dorsey S, George M, Stewart A, Lentz S, Cook C, Akmal A, Price L, Keim P, Mateczun AJ, Brahmbhatt T, Bishop-Lilly K, Zwick M, Read TD, Sozhamannan S. Rapid identification of genetic modifications in Bacillus anthracis genome using Roche 454 pyrosequencing technology. PLoS One. 2010 Aug 25; 5(8). Pii: e12397.

Mukhopadhyay S, Thomason MPK, Lentz S, Nolan N, Willner K, Gee JE, Glass ME, Inglis TJJ, Merritt A, Levy A, Sozhamannan S, Mateczun AJ, Read TD. High redundancy draft sequencing of 15 clinical and environmental Burkholderia strains. J Bacteriol. 2010 Dec; 192(23):6313-4. Epub 2010 Sep 24.

Bishop-Lilly KA, Turell MJ, Willner KM, Butani A, Nolan NME, Lentz SM, Akmal A, Mateczun AJ, Brahmbhatt TN, Sozhamannan S, Whitehouse CA, Read TD. Arbovirus detection in insect vectors by rapid, high-throughput pyrosequencing. PLoS Negl Trop Dis. 2010 Nov 9:4(11):e878.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
The goal of the program is the development of rapid diagnostic assays which would increase the rapid detection and diagnosis of infectious diseases.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category A and B Priority Pathogens
- **Overlap Select Agents**
  Including NIAID Category A and B Priority Pathogens

[*] Including viruses and prions.

III. Outdoor Studies:
None

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Naval Research Laboratory (NRL)

2. Where is it located (provide both address and geographical location)?

4555 Overlook Ave., SW
Washington District of Columbia 20375

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	1305
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	1305

4. The organizational structure of each facility.

I Total Number of Personnel 61

II Division of Personnel:

Military	2
Civilian	59

III Division of Personnel by Category:

Scientists	51
Engineers	6
Technicians	4
Administrative/Support	0

IV List the scientific disciplines represented in the scientific/engineering support staff.

Biochemistry
Biology
Biophysics
Chemical Engineering
Chemistry
Electrical Engineering

Engineering
Immunology
Mechanical Engineering
Microbiology
Molecular Biology
Physics

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 24

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)

VII What are the funding levels for the following program areas:

Research	$5,938,000
Development	$2,372,000
Test and evaluation	$ 82,000
Total	$8,392,000

VIII Briefly describe the publication policy of the facility:

Unlimited release, prefer peer reviewed journals for research results; limit to Government for test and evaluation and proprietary data.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Anderson G.P., Zabetakis, D., Bernstein, R.D., Cai, S., Singh, B.R., Goldman, E.R. 2010 Evaluation of Anti-Hemagglutinin Hn-33 Single Domain Antibodies, The Botulinum Journal, In Press.

Anderson, G.P., Bernstein, R.D., Swain, M.D., Zabetakis, D., Goldman E.R. 2010 Binding Kinetics of Antiricin Single Domain Antibodies and Improved Detection Using a B Chain Specific Binder. Analytical Chemistry 82: 7202-7207.

Anderson GP, Kowtha VA, Taitt CR. 2010. Detection of fumonisin B1 and ochratoxin A in grain products using microsphere-based fluid array immunoassays. Toxins 2, 297-309.

Goldman E.R. Anderson, G.P., Bernstein, R.D., Swain, M.D. 2010 Amplification of

Immunoassays using Phage-Displayed Single Domain Antibodies Journal of Immunological Methods 352: 182-185.

Mansoor Nasir, Daniel A. Ateya, Diana Burk, Joel P. Golden, Frances S. Ligler, "Hydrogynamic focusing of conducting fluids for conductivity-based biosensors", Biosensors and Bioelectronics 25 (2010) 1363 -1369.

Nasir M., Price, D.T., Shriver-Lake, L.C., and Ligler, F., "Effect of diffusion on impedance measurements in a hydrodynamic flow focusing sensor" Lab on a Chip, 10, 2787-2795.

North, SH (North, Stella H.); Lock, EH (Lock, Evgeniya H.); King, TR (King, Tiffany R.); Franek, JB (Franek, James B.); Walton, SG (Walton, Scott G.); Taitt, CR (Taitt, Chris R.), Effect of Physicochemical Anomalies of Soda-Lime Silicate Slides on Biomolecule Immobilization, ANALYTICAL CHEMISTRY, 82 (1): 406-412 JAN 1 2010. ISSN: 0003-2700 DOI: 10.1021/ac902324r.

Thangawng, A.L., Kim, J.S., Golden, J.P., Anderson, G.P., Robertson, K.L., Low, V., Ligler, F.S. 2010 A PMMA Cytometer using Groove-generated Sheath Flow for Multiplexed Bead and Cell Assays. Analytical and Bioanalytical Chemistry 398: 1871-1881 DOI 10.1007/s00216-010-4019-7.

Swain M.D., Anderson G.P., Zabetakis D., Bernstein R.D., Liu J.L., Sherwood L.J., Hayhurst A., Goldman E.R. 2010 Llama-derived single-domain antibodies for the detection of botulinum A neurotoxin. Analytical and Bioanalytical Chemistry 398: 339-348.

D. Andrew Knight, Thomas E. Hickeya, Jason E. Bongard, Dzung C. Thach, R. Yngard and Eddie L. Chang, "Differential effects of Co(III), Ni(II), and Ru(III) amine complexes on Sindbis virus," Journal of Inorganic Biochemistry, 104, 592-598 (2010).

Wang Z, Malanoski AP, Lin B, Long NC, Leski TA, Blaney KM, Hansen CJ, Brown J, Broderick M, Stenger DA, Tibbetts C, Russell KL, Metzgar D. "Broad Spectrum Respiratory Pathogen Analysis of Throat Swabs from Military Recruits Reveals Interference Between Rhinoviruses and Adenoviruses." Microb Ecol. 2010 59, 623-634.

B. Lin, B.J. Johnson, R.A. Rubin, A.P Malanoski, F.S. Ligler. "Iron Chelation Capability of Cranberry Juice and Its Impact on Escherichia Coli Growth" BioFactors (2010) in press.

John Cooper, Nina Yazvenko, Kia Peyvan, Karl Maurer, Chris R. Taitt, Wanda Lyon, David L. Danley, "Targeted Deposition of Anitbodies on a Multiplex CMOS Microarray and Optimization of a Sensitive Immunoassay Using Electrochemical Detection", PLoS ONE, March 2010, Vol. 5, Issue 3, e9781.

North SH, Lock EH, Taitt CR, Walton SG. 2010. Critical parameters in biointerface design and their impact on biosensor development. Anal Bioanal Chem 397, 925-933.

Lin, B; Wang, Z; Malanoski, AP; O'Grady, EA; Wimpee, CF; Vuddhakul, V; Alves Jr., N; Thompson, FL; Gomez-Gil, B; Vora, GJ "Comparative genomic analyses identify the Vibrio harveyi genome sequenced strains BAA-1116 and HY01 as Vibrio campbellii," ENVIRONMENTAL MICROBIOLOGY REPORTS, 2010, 2(1): 81-89.

Metzgar, D., Myers, C. A., Russell, K. L., Faix, D. Blair, P. J., Brown, J., Vo, S., Swayne, D. E., Thomas, C., Stenger, D. A., Lin, B., Malanoski, A. P., Wang, Z., Blaney, K. M., Long, N. C., Schnur, J. M., Saad, M. D., Borsuk, L. A., Lichanska, A. M., Lorence, M. C., Weslowski, B., Schafer, K. O., Tibbetts, C. Single assay for simultaneous detection and differential identification of human and avian influenza virus types, subtypes, and emergent variants. (2010) PLos One. February 3; 5(2):e8995.

Leski, T. A., Malanoski, A. P., Stenger, D. A., Lin, B. Target amplification for broad spectrum microbial diagnostics and detection. (2010) Future Microbiol. 5, 191-203.

Slocik J.M., Kim S.N., Auvil T., Goldman E.R., Liu J., and Rajesh R. Naik R.R. 2010. Single Domain Antibody Templated Nanoparticle Resistors for Sensing Biosensors and Bioelectronics 25: 1908-1913.

Wojciechowski J, Danley D, Cooper J, Yazvenko N, Taitt CR. 2010. Multiplexed electrochemical detection of Yersinia pestis and staphylococcal enterotoxin B using an antibody microarray. Sensors 10(4), 3351-3362.

Walton SG, Lock EH, Baraket M, Boris DR, Fernsler RF, North SH, Taitt CR, Robinson JT, Perkins FK, Sheehan PE. Plasma processing of ion energy-sensitive materials. NRL Review 2010.

Silveira A.C., Robertson K.L., Lin B., Wang Z., Vora G.J., Vasconcelos A.T., Thompson F.L. "Identification of non-coding RNAs in environmental vibrios" Microbiology (2010) May 6.

Archer, M. J., Long, N., Lin, B. Effect of probe characteristics on the subtractive hybridization efficiency of human genomic DNA. (2010) BMC Res. Notes 3, 109.

Kim JS, Taitt CR, Ligler FS, Anderson GP. 2010. Multiplexed magnetic microsphere immunoassays for detection of pathogens in foods. Sens Instr Food Qual 4, 73-81.

K.L. Robertson, A.B. Verhoeven, D. Thach, and E. Chang. (2010) "Monitoring Viral RNA in Infected Cells with LNA Flow-FISH." RNA; 16: 1679-1685.

Soto CM, Ratna BR "Virus hybrids as nanomaterials for biotechnology" Curr Opin Biotech 2010, 21:1-13. (Invited Review), Cover Page.

North SH, Lock EH, Cooper CJ, Franek JB, Taitt CR, Walton SG. Plasma-based surface modification of polystyrene microtitre plates for covalent immobilization of biomolecules.

Appl Mater Interfac, doi: 10.1021/am100566e.

Wojciechowski, J, Chase-Baldwin K, Wasieloski LP Jr, Padilla S, Vora GJ, and Taitt CR. Enhancement of DNA microarray performance using post-hybridization signal amplification. Anal. Chim. Acta, doi:10.1016/j.aca.2010.09.007.

Prasuhn, D.E., Deschamps, J.R., Susumu, K., Boeneman, K., Blanco-Canosa, J.B., Dawson, P.E., and Medintz, I.L., "Polyvalent Display and Packing of Peptides and Proteins on Semiconductor Quantum Dots: Predicted Versus Experimental Results", Small, 6(4), 555-564 (2010).

Eddie L. Chang, Christa Simmers, and D. Andrew Knight, "Cobalt Complexes as Antiviral and Antibacterial Agents", Pharmaceuticals, 3, 1711-1728 (2010).

F.S. Ligler, J. S. Erickson, J. P. Golden, J. S. Kim, M. Nasir, P. B. Howell, A. L. Thangawng, L. R. Hilliard, L. C. Shriver-Lake and G. P. Anderson, "A multiwavelength microflow cytometer", NRL Review, 2010, 152-154.

Kim, J.S. and F.S. Ligler (2010) Utilization of microparticles in next-generation assays for microflow cytometers. Anal. Bioanal. Chem. 398, 2373-2382.

Vasanthi Sivaprakasam, Alan L. Huston, Abraham Schultz and Jay D. Eversole, "A novel method of aerosol particle velocimetry using polarized elastic scattering", (in preparation for Aerosol Science and Technology).

J. D. Eversole, T. Pierce, and J. E. Tucker, "Biological Aerosol Detection Algorithm Development," NRL/PU/5590-10-542, pg 32-33, 2010.

V. Sivaprakasam, J. Luo, M. Currie, and J. D. Eversole, "Two-photon excited fluorescence from biological aerosol particles," submitted to Journal of Quantitiative spectroscopy and Radiative Transfer (2010).

J.W. Lou, M. Currie, V. Sivaprakasam, and J.D. Eversole. 2010. Green and ultraviolet pulse generation with a compact, fiber laser, chirped-pulse amplification system for aerosol fluorescence measurements", Rev. Sci. Instrum. 81 (9).

J. D. Eversole, C. Scotto, P. Berry, J. Gebhardt, T. Hadfield, P. Hitchcock, R. McCandliss, A. Samuels, and M. Walters, "Impact of Weaponization Methods on BWA Sensor Performance," Final Report of the Weaponization Assessment Panel, Defense Threat Reduction Agency Contract # CO05DET039; submitted 7/30/2010.

Alex Terray, Sean J. Hart, "Off-the-Shelf 3D Microfluidic Nozzle", Lab on a Chip, 10 (13), 1729-1731, 2010.

Joseph D. Taylor, Alex Terray, and Sean J. Hart, "Analytical Particle Measurements in an

Optical Microflume", Analytica Chimica Acta, 670 (1-2), 78-83, 2010.

A. A. Lall, A. Terray, and S. J. Hart, "On-the-fly cross flow laser guided separation of aerosol particles based on size, refractive index and density - theoretical analysis", Optics Express, 18, 26775-26790, 2010.

R. Stine, J. T. Robinson, P. E. Sheehan, C. R. Tamanaha, Real-time DNA detection using reduced graphene oxide field effect transistors, Adv. Mater. 22 (2010) 5297-5300; doi: 10.1002/adma.201002121.

B. J. Yakes, S. M. Etheridge, S. P. Mulvaney, and C. R. Tamanaha. Fluidic Force Discrimination assays: A new technology for tetrodotoxin detection, Marine Drugs 8 (2010) 565-576; doi: 10.3390/md8030565.

R. Stine, B. S. Simpkins, S. P. Mulvaney, L. J. Whitman, and C. R. Tamanaha. Formation of amine groups on the surface of GaN: A method for direct biofunctionalization, Appl. Surf. Sci. 256 (2010) 4171-4175; doi: 10.1016/j.apsusc.2010.01.120.

M. B. Hart, A. Makoui, H B. Lin, and J. D. Eversole, "Advances in On-the-Fly Labeling of Chemical and Biological Aerosols for Rapid Detection and Identification," PITTCON 2010, Orlando, FL, March 1, 2010.

J. D. Eversole, A. Schultz, V. Sivaprakasam, W. C. Jacobson, J. E. Tucker, P. Falkenstein, J. Willey, T. Pierce, R. Pierson, and M. C. Ertem, "Optical biological aerosol characterization: autonomous classification and detection algorithm development," 2010 DTRA-NSF Algorithm Workshop, Raleigh, NC, June 21-24, 2010.

V. Sivaprakasam, J. Czege, J. Luo, M. Currie, and J. D. Eversole, "Fluorescence from biological aerosol particles using mode-locked pulses: one and two photon excitation," Pittcon, Orlando, Fl, March 2010.

"Real-time monitoring of biological interactions with chemically-modified graphene FETs," R. Stine, J. T. Robinson, P. E. Sheehan, C. R. Tamanaha, Materials Research Society Fall 2010 Meeting, Boston, MA, 29 Nov.-3 Dec. 2010.

"Label-free biosensing with a 2-dimensional electron gas," R. Stine, S. Mulvaney, J. Rife, C. Tamanaha, 2010 Chemical and Biological Defense Science and Technology Conference, Orlando, FL, 15-19 November 2010.

"Stochastic sensing with quantum well devices, BAS-BRC07-N-2-0049," C. R. Tamanaha, DTRA Chemical and Biological Defense Basic Research Technical Review, Springfield, VA, 13 August 2010.

"A biosensor's 10+ year odyssey at NRL from an innovative idea through technology transfer," S. P. Mulvaney, Gordon Conference on Bioanalytical Sensors, Colby-Sawyer

College, New London, NH 20-25 June 2010.

"Rapid screening for seafood toxins with competitive fluidic force discrimination (cFFD) assays," S. P. Mulvaney, B. J. Yakes, S. Etheridge, C. R. Tamanaha, 20th Anniversary World Congress on Biosensors, Glasgow, UK, 26 May 2010.

"Label and label-free biosensing strategies at NRL," C. R. Tamanaha, S. P. Mulvaney, J. C. Rife, R. Stine, 1st Tri-Service Biotechnology Technical Planning Meeting, Potomac, MD, 23-24 February 2010.

"Fluidic force discrimination assays: an alternative technology for rapid and sensitive food monitoring," S. P. Mulvaney, B. J. Yakes, S. Etheridge, C. R. Tamanaha, International Forum on Process Analytical Chemistry, Baltimore, MD, 3 February 2010.

Taitt, C.R., Shriver-Lake, L.C., Anderson, G.P., Ligler, F.S. Surface modification and biomolecule immobilization on polymer spheres for biosensing applications. Methods in Molecular Biology: Biomedical Nanotechnology: Methods and Protocols, Sarah J. Hurst (editor), in press.

Leski, T. A., Malanoski, A. P., Wang, Z., Stenger, D. A., Lin, B. (2010). "Analysis of dust samples from the Middle East using high density resequencing Microarray "RPM-TEI" Proceeding of SPIE- The international Society for Optical Engineering. 7666, 76661E1-E11.

Mansoor Nasir, Gusphyl Justin, Lisa C. Shriver-Lake, Joel P. Golden, Frances S. Ligler (2010), “Hydrodynamic Focusing for Improved Sensitivity of an Impedance-based Sensor for Cell Detection and Analysis", Proceeding of µTAS 2010, Chemical and Biological Microsystems Society, Groningen, The Netherlands, p446.

Golden, J. P., Kim, J., Anderson, G. P., Hashemi, N., Howell, P. J., and Ligler, F. S. (2010) A microflow cytometer on a chip, (Philippe, M. F., and Benjamin, L. M., Eds.), p 755308, SPIE.

Hashemi, N., Howell, P. J., Golden, J. P., Erickson, J., and Ligler, F. S. (2010) Microflow cytometer: hydrodynamic focusing and separation of sample stream, in ASME International Mechanical Engineering Congress, Vancouver, Canada.

Lock EH, North SH, Wojciechowski J, Taitt CR, Walton SG. 2010. Exploring the mechanism of biomolecule immobilization on plasma-treated polymer substrates. Proc. NATO Conf. Tech Innov Detect Sens Chem Biol Nucl Ecol Terr, Moldova, Jun 2010.

"Real-time monitoring of biological interactions with chemically-modified graphene FETs," R. Stine, J. T. Robinson, P. E. Sheehan, C. R. Tamanaha, Materials Research Society Fall 2010 Meeting, Boston, MA, 29 Nov.-3 Dec. 2010.

"Rapid screening for seafood toxins with competitive fluidic force discrimination (cFFD)

assays," S. P. Mulvaney, B. J. Yakes, S. Etheridge, C. R. Tamanaha, 20th Anniversary World Congress on Biosensors, Glasgow, UK, 26 May 2010.

United States Patent 7,695,941 "MULTIPLEXED POLYMERASE CHAIN REACTIONFOR GENETIC SEQUENCE ANALYSIS" by Lin, B., Blaney, K. M., Malanoski, A. P., Schnur, J. M., Stenger, D. A. issued on April 13, 2010.

United States Patent 7,668,664 "DESIGN AND SELECTION OF GENETIC TARGETS FOR SEQUENCE RESOLVED ORGANISM DETECTION AND IDENTIFICATION" by Malanoski, A. P., Wang, Z, Lin, B., Stenger, D. A., Schnur, J. M., issued on February 23, 2010.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
The objectives are to develop and test reliable systems for the detection of biological warfare agents in order to provide early warning and contamination avoidance information.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category B Priority Pathogens
- **Other pathogens or toxins**
  Including non-Select Agent, NIAID Category B Priority Pathogens

III. Outdoor Studies:
None

[*] Including viruses and prions.

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Naval Surface Warfare Center-Dahlgren Division

2. Where is it located (provide both address and geographical location)?

6149 Welsh Road
Dahlgren Virginia 22448-5162

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	190
BL3 (sqM)	26
BL4 (sqM)	0
Total (sqM)	216

4. The organizational structure of each facility.

I Total Number of Personnel 172

II Division of Personnel:

Military	0
Civilian	172

III Division of Personnel by Category:

Scientists	66
Engineers	52
Technicians	13
Administrative/Support	41

IV List the scientific disciplines represented in the scientific/engineering support staff.

Aerospace Engineering
Biology
Chemical Engineering
Chemistry
Computer Engineering
Computer Science
Electronic Engineering

General Engineering
Industrial Engineering
Mathematics
Mechanical Engineering
Microbiology
Molecular Biology
Operations Research Analyst
Physical Science
Physics
Software Engineering
Toxicology

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 23

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)
Internal (Laboratory Directed Research and Development LDRD)
Other Governmental Agencies
Private Sector Companies

VII What are the funding levels for the following program areas:

Research	$ 4,719,000
Development	$ 3,524,000
Test and evaluation	$ 9,700,000
Total	$17,943,000

VIII Briefly describe the publication policy of the facility:

Employees are encouraged to publish. Employees must follow appropriate U.S. DoD guidelines for publishing information related to biological defense efforts and have all publications approved.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Beck, L.C., Biotoxin Test Method Development, Abstract, March 2010.

Beck, L.C., Integrating BioWatch Quality Assurance Activities with the Naval Surface

Warfare Center Dahlgren Division Biological Defense Quality Assurance Sample Laboratory, Abstract, June 2010.

Beck, L.C., Integrating BioWatch Quality Assurance Activities with the Naval Surface Warfare Center Dahlgren Division Biological Defense Quality Assurance Sample Laboratory, Presentation, August 2010.

Buhr, T., Decontamination of Bacillus anthracis spores using electrochemically generated liquid-phase chlorine dioxide (eClO2), Publication, October 2010.

Buhr, T., Hot Air Decontamination of Bacillus Spores JBADS (Joint Biological Agent Decontamination System) Program, Abstract, June 2010.

Buhr, T., Hot Air Decontamination (HAD) of Bacillus Spores; JBADS (Joint Biological Agent Decontamination System) Program, Presentation, September 2010.

Clark, W., FDNY CBRN System Operations and Maintenance Manual, Publication, April 2010.

Cusworth, B., H1N1 Diagnostic Capability via the Joint Biological Agent Identification Diagnostic System (JBAIDS), Abstract, July 2010.

Cusworth, B., H1N1 Diagnostic Capability via the Joint Biological Agent Identification Diagnostic System (JBAIDS), Publication, October 2010.

Gutting, B. and R. Mackie, Benchmark Dose Analysis for Bacillus anthracis Low Dose Exposure Data in the Rabbit and its Application to the Development of Remedial Targets, Abstract/Poster, January 2010.

Gutting, B. and R. Mackie, Characterization of the Host Response to Sub-lethal Challenge Doses of Bacillus anthracis Spores in the New Zealand White Rabbit Model of Inhalational Anthrax, Abstract/Poster, January 2010.

Gutting, B., Microtiter Plate Lid to Mitigate Cell Distribution Bias from Meniscus Edge, Publication, January 2010.

Gutting, B., Multiple Low Dose Bacillus anthracis Inhalation Exposures in the Rabbit, Abstract, November 2010.

Hodge, R.C., Patent: "Aqueous Based Chemical and Biological Warfare Decontaminating System For Extreme Temperature Applications", Publication, March 2010.

Hunt, J.R., CBD S&T 2010 Abstract, Abstract, June 2010.

Hunt, J.R., JSTO-CBD-Poster, Presentation, November 2010.

Hunt, J.R., ONR Capability Slide, Presentation, November 2010.

Kota, D., Investigating Flavonoids as Radioprotective Agents, Presentation/Abstract, June 2010.

Mackie, R., Bacillus anthracis Interacts with Plasmin(ogen) to Evade C3b-dependent Innate Immunity, Publication, November 2010.

McPherson, D., Spore Surface Characterization, Abstract, June 2010.

McPherson, D., Spore Surface Characterization, Presentation, August 2010.

McPherson, D., Bacillus Spore Characterization, Publication, October 2010.

Parish, S., CBR Defense Systems, Publication, August 2010.

Wells, C., Solid Oxidizer Development, Abstract, June 2010.

Wells, C., Solid Oxidizer Development, Publication, September 2010.

Wells, C., Solid Oxidizer Development: Solid Peracetic Acid, Publication, November 2010

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
Efforts at this defense laboratory are focused on biological detection systems, collective and individual protection systems, hazard mitigation technologies, risk assessment tools and consequence management planning.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category A and B Priority Pathogens
- **Overlap Select Agents**
  Including NIAID Category A Priority Pathogens
- **Other pathogens or toxins**

[*] Including viruses and prions.

III. Outdoor Studies:
Performance testing of detectors using powdered egg protein and smoke at known distances to gather data on proximity of detection.

Form A, Part 2 (iii)

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Tyndall AFB -- 1

2. Where is it located (provide both address and geographical location)?

3000 Research Road
Tyndall AFB Florida 32403

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	55
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	55

4. The organizational structure of each facility.

I Total Number of Personnel 5

II Division of Personnel:

Military	0
Civilian	5

III Division of Personnel by Category:

Scientists	3
Engineers	0
Technicians	2
Administrative/Support	0

IV List the scientific disciplines represented in the scientific/engineering support staff.

Microbiology

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 4

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)
U.S. Department of Homeland Security (DHS)
Other Governmental Agencies

VII What are the funding levels for the following program areas:

Research	$800,000
Development	$ 0
Test and evaluation	$150,000
Total	$950,000

VIII Briefly describe the publication policy of the facility:

Unlimited release, prefer peer reviewed journals for research results; limit to U.S. Government for test and evaluation and proprietary data.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Stone, B.; Consistency and Reproducibility of Bioaerosol Delivery for Infectivity Studies on Mice; AFRL-RX-TY-TP-2010-0037.

Wander, J.; Evaluation of Multiple (3-Cycle) Dexontamination Processing for Filtering Facepiece Respirators; AFRL-RX-TY-TP-2010-0008.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
The facility houses and supports a bioaerosol test chamber in which aerosols containing biological simulants are used to classify the size distribution of bioaerosol challenges as needed.

II. Agents Microorganisms and/or Toxins:

- **Other pathogens or toxins**
  Including non-Select Agent, NIAID Category B Priority Pathogens

* Including viruses and prions

III. Outdoor Studies:
None

Form A, Part 2 (iii)

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Tyndall AFB -- 2

2. Where is it located (provide both address and geographical location)?

139 Barnes Drive
Tyndall AFB Florida 32403

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	53
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	53

4. The organizational structure of each facility.

I Total Number of Personnel 7

II Division of Personnel:

Military	0
Civilian	7

III Division of Personnel by Category:

Scientists	3
Engineers	1
Technicians	1
Administrative/Support	2

IV List the scientific disciplines represented in the scientific/engineering support staff.

Chemistry
Environmental Engineering

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 5

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)

VII What are the funding levels for the following program areas:

Research	$1,000,000
Development	$1,300,000
Test and evaluation	$ 0
Total	$2,300,000

VIIIBriefly describe the publication policy of the facility:

Unlimited release, prefer peer reviewed journals for research results; limit to U.S. Government for test and evaluation and proprietary data.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

None

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
This facility supports the preparation and characterization of novel chemicals expected to exhibit antimicrobial properties. It also supports research into degradation products formed by exposure of samples of reactive materials to surrogate threat agents.

II. Agents Microorganisms and/or Toxins:
None

III. Outdoor Studies:
None

* Including viruses and prions.

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

U.S. Army Edgewood Chemical and Biological Center

2. Where is it located (provide both address and geographical location)?

5183 Blackhawk Road
Aberdeen Proving Ground Maryland 21010-5424

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	532
BL3 (sqM)	177
BL4 (sqM)	0
Total (sqM)	709

4. The organizational structure of each facility.

I Total Number of Personnel 263

II Division of Personnel:

Military	0
Civilian	263

III Division of Personnel by Category:

Scientists	168
Engineers	39
Technicians	27
Administrative/Support	29

IV List the scientific disciplines represented in the scientific/engineering support staff.

Aerobiology
Aerospace Engineering
Biochemistry
Biological Science
Biology
Biomedical Engineering

Biotechnology
Chemical Engineering
Chemistry
Computer Engineering
Electronic Engineering
General Engineering
Immunology
Mathematics
Mechanical Engineering
Microbiology
Molecular Biology
Operations Research Analysis
Physical Science
Physics
Physiology
Statistics
Toxicology
Toxinology
Virology

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 155

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)

VII What are the funding levels for the following program areas:

Research	$ 1,204,000
Development	$22,145,000
Test and evaluation	$ 0
Total	$23,349,000

VIII Briefly describe the publication policy of the facility:

Publications are prepared in accordance with Army regulations. Scientists are encouraged to publish their results in peer reviewed scientific literature as well as present their work at national and international professional meetings.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Ben-David A, Sagripanti JL. A model for inactivation of microbes suspended in the atmosphere by solar ultraviolet radiation. Photochem. Photobiol., 86(4):895-908, Jul-Aug 2010. Epub May 13, 2010.

Bevilacqua VL. Nilles JM, Rice JS, Connell TR, Schenning AM, Reilly LM, Durst HD. Ricin activity assay by direct analysis in real time mass spectrometry detection of adenine release. Anal. Chem., 82(3):798-800, Feb 1, 2010.

Carrieri AH, Copper J, Owens DJ, Roese ES, Bottiger JR, Everly RD 2nd, Hung KC. Infrared differential-absorption Mueller matrix spectroscopy and neural network-based data fusion for biological aerosol standoff detection. Appl. Opt., 49(3):382-393, Jan 20, 2010. doi: 10.1364/AO.49.000382.

Chambers AE, Dixon MM, Harvey SP. Studies of the suitability of fowlpox as a decontamination and thermal stability stimulant for variola major. Int. J. Microbiol., 2009:158749, Epub Jan 28, 2010.

Edmonds J, Clark P, Williams L, Lindquist HD, Martinez K, Gardner W, Shadomy S, Hornsby-Myers J. Multigeneration cross contamination of mail with Bacillus species spores by tumbling. Appl. Environ. Microbiol., 76(14):4797-4804, Jul 2010. Epub May 28, 2010.

Jabbour RE, Deshpande SV, Stanford MF, Wick CH, Zulich AW, Snyder AP. A protein processing filter method for bacterial identification by mass spectrometry-based proteomics. J. Proteome. Res., Dec 20, 2010 (Epub ahead of print].

Jabbour RE, Wade MM, Deshpande SV, Stanford MF, Wick CH, Zulich AW, Snyder AP. Identification of Yersinia pestis and Escherichia coli strains by whole cell and outer membrane protein extracts with mass spectrometry-based proteomics. J. Proteome. Res., 9(7):3647-3655, Jul 2, 2010.

Jabbour RE, Deshpande SV, Wade MM, Stanford MF, Wick CH, Zulich AW, Skowronski EW, Snyder AP. Double-blind characterization of non-genome-sequenced bacteria by mass spectrometry-based proteomics. Appl. Environ. Microbiol., 76(11):3637-3644, Jun 2010. Epub Apr 2, 2010.

Rastogi VK, Ryan SP, Wallace L, Smith LS, Shah SS, Martin GB. Synthetic evaluation of the efficacy of chlorine dioxide in decontamination of building interior surfaces contaminated with anthrax spores. Appl. Environ. Microbiol., 76(10):3343-3351, May 2010. Epub Mar 19, 2010.

Sagripanti JL, Lytle CD. Sensitivity to ultraviolet radiation of Lassa, vaccinia, and Ebola

viruses dried on surfaces. Arch. Virol., Nov 23, 2010 [Epub ahead of print].

Sagripanti JL, Carrera M, Robertson J, Levy A, Inglis TJ. Size distribution and buoyant density of Burkholderia pseudomallei. Arch. Micorobiol., 193(1):69-75, Jan 2011. Epub Nov 16, 2010.

Sagripanti JL, Rom AM, Holland LE. Persistence in darkness of virulent alphaviruses, Ebola virus, and Lassa virus deposited on solid surfaces. Arch. Virol., 155(12):2035-2039, Dec 2010. Epub Sep 15, 2010.

Wade MM, Chambers AE, Insalaco JM, Zulich AW. Survival of viral biowarfare agents in disinfected waters. Int. J. Microbiol., 2010:412694. Epub Dec 16, 2010.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
Development of non-medical defensive material against biological agents to include: research, development, and engineering for methods of rapid detection, identification, decontamination, and physical protection of/from biological threat agents.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category A, B and C Priority Pathogens
- **Overlap Select Agents**
  Including NIAID Category A and B Priority Pathogens
- **Other pathogens or toxins**
  Including non-Select Agent, NIAID Category B Priority Pathogens

III. Outdoor Studies:
None

* Including viruses and prions.

Form A, Part 2 (iii)

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

U.S. Army Edgewood Chemical and Biological Center (ECBC)

2. Where is it located (provide both address and geographical location)?

U.S. Army Edgewood Chemical and Biological Center
5183 Blackhawk Rd
Aberdeen Proving Ground Maryland 21010-5424

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	2000
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	2000

4. The organizational structure of each facility.

I Total Number of Personnel 6

II Division of Personnel:

Military	0
Civilian	6

III Division of Personnel by Category:

Scientists	3
Engineers	3
Technicians	0
Administrative/Support	0

IV List the scientific disciplines represented in the scientific/engineering support staff.

Aerosol Science
Biology
Chemistry
Engineering
Materials Science
Physics

Polymer Science

V Are contractor staff working in the facility? If so, provide an approximate number.

No

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)

VII What are the funding levels for the following program areas:

Research	$ 0
Development	$ 0
Test and evaluation	$1,171,000
Total	$1,171,000

VIIIBriefly describe the publication policy of the facility:

The publication policy requires prior review by Edgewood Chemical Biological Center's public affairs and security offices prior to submission.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

None

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
Conduct mixed reactor testing for the evaluation of the efficacy of the countermeasure solution against a biological warfare agent simulant to determine if agent neutralization can be achieved.

II. Agents Microorganisms and/or Toxins:

- **Other pathogens or toxins**

* Including viruses and prions.

III. Outdoor Studies:
None

Form A, Part 2 (iii)

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

U.S. Army Medical Research Institute of Chemical Defense (USAMRICD)

2. Where is it located (provide both address and geographical location)?

3100 Ricketts Point Road
Aberdeen Proving Ground, Maryland 21010-5400

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	300
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	300

4. The organizational structure of each facility.

I Total Number of Personnel 11

II Division of Personnel:

Military	2
Civilian	9

III Division of Personnel by Category:

Scientists	5
Engineers	0
Technicians	6
Administrative/Support	0

IV List the scientific disciplines represented in the scientific/engineering support staff.

Biochemistry
Biology
Molecular Biology
Pharmacology
Physiology

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 5

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)

VII What are the funding levels for the following program areas:

Research	$ 422,000
Development	$ 630,000
Test and evaluation	$ 0
Total	$1,052,000

VIII Briefly describe the publication policy of the facility:

Publications are prepared and published in accordance with Army regulations.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

McNutt,MM, Celver, JP, Hamilton, TA, and Mesngon, MT (2010). Embryonic stem cell-derived neurons are a novel, highly sensitive tissue culture platform for Botulinum research. Biochemical and Biophysical Research Communications.

Adler, M, Deshpande, SS and Apland JP. (2010). Simultaneous or sequential administration of botulinum neurotoxin E does not reduce the duration of paralysis caused by botulinum neurotoxin A in the rat EDL muscle. The botulinum Journal.

Lebeda, F.J. and Adler, M. (2010). Hydrodynamic models for the diffusivity of type A botulinum neurotoxin. The Botulinum Journal.

Potian, JG, Thyagarajan, B, Lebeda, FJ, Schmidt, JJ, Adler, M and McArdle, JJ (2010). Investigation of CRARKML derived peptides as antidotes for the in vivo and in vitro paralytic effect of botulinum neurotoxin A. The Botulinum Journal.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols.

* Including viruses and prions.

I. Objectives:
The Institute's mission involves research on medical defenses against neurotoxins.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category A Priority Pathogens

III. Outdoor Studies:
None

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID)

2. Where is it located (provide both address and geographical location)?

1425 Porter Street
Fort Detrick
Frederick, Maryland 21702-5011

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	26026
BL3 (sqM)	3139
BL4 (sqM)	1093
Total (sqM)	30258

4. The organizational structure of each facility.

I Total Number of Personnel 826

II Division of Personnel:

Military	193
Civilian	633

III Division of Personnel by Category:

Scientists	256
Engineers	3
Technicians	310
Administrative/Support	257

IV List the scientific disciplines represented in the scientific/engineering support staff.

Aerobiology
Biochemistry
Biology
Chemistry
Clinical Immunology

Entomology
Genetics
Immunology
Infectious Disease
Internal Medicine
Microbiology
Molecular Biology
Preventive Medicine
Toxicology
Veterinary Medicine
Virology

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 255

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)

VII What are the funding levels for the following program areas:

Research	$ 5,100,000
Development	$58,324,000
Test and evaluation	$ 0
Total	$63,424,000

VIII Briefly describe the publication policy of the facility:

Publications are prepared in accordance with Army regulations. Scientists are encouraged to publish their results in peer reviewed scientific literature as well as present their work at national and international professional meetings.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Alves DA, AR Glynn, KE Steele, MG Lackmeyer, NL Garza, JG Buck, C Mech, DS Reed. 2010. Aerosol exposure to the Angola strain of Marburg virus causes lethal viral hemorrhagic fever in cynomolgus macaques. Vet Pathol 47:831 - 851.

Bradfute SB, PE Swanson, MA Smith, E Watanabe, JE McDunn, RS Hotchkiss, S Bavari. 2010. Mechanisms and consequences of ebolavirus-induced lymphocyte apoptosis. J

Immunol 184:327 - 335.

Chapman JL, DK Nichols, MJ Martinez, JLW Raymond. 2010. Animal models of Orthopoxvirus infection. Vet Pathol 47:852 - 870.

Eppinger M, PL Worsham, MP Nikolich, DR Riley, Y Sebastian, S Mou, M Achtman, LE Lindler, J Ravel. 2010. Genome sequence of the deep-rooted *Yersinia pestis* strain Angola reveals new insights into the evolution and pangenome of the plague bacterium. J Bacteriol (epub ahead of print).

Heine HS, BK Purcell, J Bassett, BP Goldstein. 2010. Activity of dalbavancin against *Bacillus anthracis* in vitro and in a mouse inhalation anthrax model. Antimicrob Agents Chemother (epub ahead of print).

Lebeda FJ, RZ Cer, RM Stephens, U Mudunuri. 2010. Temporal characteristics of botulinum neurotoxin therapy. Expert Rev Neurother 10:93 - 103.

Little SF, WM Webster, H Wilhelm, D Fisher, SL Norris, BS Powell, J Enama, JJ Adamovicz. 2010. Quantitative anti-F1 and anti-V IgG ELISAs as serological correlates of protection against plague in female Swiss Webster mice. Vaccine (epub ahead of print).

Ludivico ML, LA Smith, SA Ahmed. 2010. Structure-based design of peptide inhibitors of botulinum neurotoxin serotypes A proteolytic activity. Botulinum J 1:297 - 307.

Martin GJ, AM Friedlander. 2010. Anthrax as an agent of bioterrorism, pp 3983 - 3992. *In* Mandell, Bennet, Dolin (ed), Principles and Practice of Infectious Diseases, Elsevier.

Matchett MR, DE Biggins, V Carlson, B Powell, T Rocke. 2010. Enzootic plague reduces black-footed ferret (*Mustela nigripes*) survival in Montana. Vector Borne Zoo Dis 10:37 - 35.

Mitchell JL, N Chatwell, D Christensen, H Diaper, TD Minogue, TM Parsons, B Walker, SA Weller. 2010. Development of real-time PCR assays for the specific detection of *Francisella tularensis* ssp. *tularensis*, *holarctica* and *mediaasiatica*. Mol Cel Probes (epub ahead of print).

Nuss JE, G Ruthel, LE Tressler, LM Wanner, E Torres-Melendez, ML Hale, S Bavari. 2010. Development of cell-based assays to measure botulinum neurotoxin serotype a activity using cleavage-sensitive antibodies. J Biomol Screen 15:42 - 51.

Olinger GG. 2010. Targeting biodefense markets. Hum Vaccin (epub ahead of print).

Reisler RB, DK Danner, PH Gibbs. 2010. Immunogenicity of an inactivated Japanese encephalitis vaccine (JE-VAX) in humans over 20 years at USAMRIID: Using PRNT50 as

an endpoint for immunogenicity. Vaccine 28:2436 - 2441.

Ronning CM, L Losada, L Brinkac, J Inman, RL Ulrich, M Schell, WC Nierman, D DeShazer. 2010. Genetic and phenotypic diversity in *Burkholderia*: contributions by prophage and phage-like elements. BMC Microbiol 10 202 - 219.

Sanders JL, C Lawrence, DK Nichols, JF Brubaker, TS Peterson, KN Murray, ML Kent. 2010. *Pleistophora hyphessobryconis* (Microsporidia) infecting zebrafish (*Danio rerio*) in research facilities. Dis Aqua Org 91:47 - 56.

Scorpio A, DJ Chabot, WA Day, TA Hoover, AM Friedlander. 2010. Capsule depolymerase overexpression reduces *Bacillus anthracis* virulence. Microbiology 156:1459 - 1467.

Steele KE. 2010. Guest editorial: special focus on the pathology of biological select agents and toxins in animals and research challenges in biological defense. Vet Pathol 47:772 - 773.

Steel KE, NA Twenhafel. 2010. Pathology of animal models of alphavirus encephalitis. Vet Pathol 47:490 - 805.

Thompson J, KK Hill, TJ Smith, A Pikis. 2010. Gene CBO0515 from *Clostridium botulinum* strain Hall A encodes the rare enzyme N5- (carboxyethyl) ornithine synthase, EC 1.5.1.24. J Bacteriol (epub ahead of print).

Whidby RN, S Stewart, JW Hooper, A Bertolotti-Ciarlet. 2010. Study of Andes virus entry and neutralization using a pseudovirion system. J Virol Methods (epub ahead of print).

Whitehouse CA, C Baldwin, R Sampath, LB Blyn, R Melton, F Li, V Harpin, H Matthews, M. Tediashvili, E Jaiani, T Kokashvilli, N Janelidze, C Grim, RR Colwell, A Huq. 2010. Identification of pathogenic *Vibrio* species by multilocus PCR-electrospray ionization mass spectrometry and its application to aquatic environments of the former soviet republic of Georgia. Appl Environ Microbiol 76:1996 - 2001.

Twenhafel NA. 2010. Pathology of inhalational anthrax animal models. Vet Pathol 47:819 - 830.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
To develop medical countermeasures, to include candidate vaccines, diagnostic tests and drug or immunological therapies for biological agents. Perform exploratory studies and advanced development of protective and therapeutic countermeasures and agent identification technologies.

[*] Including viruses and prions.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category A, B and C Priority Pathogens
- **Overlap Select Agents**
  Including NIAID Category A, B and C Priority Pathogens
- **USDA Select Agents and Toxins**
  Including NIAID Category A and B Priority Pathogens
- **Other pathogens or toxins**
  Including non-Select Agent, NIAID Category A, B and C Priority Pathogens

III. Outdoor Studies:
None

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Walter Reed Army Institute of Research (WRAIR)

2. Where is it located (provide both address and geographical location)?

503 Robert Grant Avenue
Silver Spring, Maryland 20910

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	294
BL3 (sqM)	165
BL4 (sqM)	0
Total (sqM)	459

4. The organizational structure of each facility.

I Total Number of Personnel 25

II Division of Personnel:

Military	3
Civilian	22

III Division of Personnel by Category:

Scientists	10
Engineers	0
Technicians	15
Administrative/Support	0

IV List the scientific disciplines represented in the scientific/engineering support staff.

Aerobiology
Biochemistry
Bioinformatics
Biology
Chemistry
Immunology

Microbiology
Molecular Biology
Veterinary Medicine

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 14

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)

VII What are the funding levels for the following program areas:

Research	$4,540,550
Development	$ 0
Test and evaluation	$ 0
Total	$4,540,550

VIII Briefly describe the publication policy of the facility:

Publications are prepared in accordance with Army regulations and receive in-house peer review before the article is published. Scientists are encouraged to publish and present their results in the open scientific literature and at scientific meetings.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Mc Gann P, Rozak DA, Nikolich MP, Bowden RA, Lindler LE, Wolcott MJ, Lathigra R. A novel brain heart infusion broth supports the study of common Francisella tularensis serotypes. J Microbiol Methods. 2010 Feb; 80(2):164-71. Epub 2009 Dec 11.

Eppinger M, Worsham PL, Nikolich MP, Riley DR, Sebastian Y, Mou S, Achtman M, Lindler LE, Ravel J. Genome sequence of the deep-rooted *Yersinia pestis* strain Angola reveals new insights into the evolution and pangenome of the plague bacterium. J Bacteriol. 2010 Mar; 192(6):1685-99. Epub 2010 Jan 8.

Ding XZ, Feng XR, Borschel RH, Nikolich MP, Feng J, Li YS, Hoover DL. HSP-70 mitigates LPS/SKI-induced cell damage by increasing sphingosine kinase 1 (SK1). Prostaglandins Other Lipid Mediat. 2010 Jun; 92(1-4):1-7. Epub 2010 Feb 1.

Weintrob AC, Roediger MP, Barber M, Summers A, Fieberg AM, Dunn J, Seldon V, Leach

F, Huang XZ, Nikolich MP, Wortmann GW. Natural history of colonization with gram-negative multidrug-resistant organisms among hospitalized patients. Infect Control Hosp Epidemiol. 2010 Apr; 31(4):330-7.

Nikolich MP, Warren RL, Lindler LE, Izadjoo MJ, Hoover DL. Attenuation of defined *Brucella melitensis wboA* mutants. Vaccine. 2010 Oct 1;28 Suppl 5:F12-6. Epub 2010 Apr1.

Sergueev KV, He Y, Borschel RH, Nikolich MP, Filippov AA. Rapid and sensitive detection of *Yersinia pestis* using amplification of plague diagnostic bacteriophages monitored by real-time PCR. PLoS One. 2010 Jun 28; 5(6):e11337.

Paranavitana C, Zelazowska E, DaSilva L, Pittman PR, Nikolich M. Th17 cytokines in recall responses against *Francisella tularensis* in humans. J Interferon Cytokine Res. 2010 Jul; 30(7):471-6.

Huang X.Z., Cash DM, Chahine MA, VAN Horn GT, Erwin DP, McKay JT, Hamilton LR, Jerke KH, Co EM, Aldous WK, Lesho EP, Lindler LE, Bowden RA, Nikolich MP. Methicillin-resistant *Staphylococcus aureus* infection in combat support hospitals in three regions of Iraq. Epidemiol Infect. 2010 Aug 23:1-4. [Epub ahead of print].

Huang, X.Z., J.G. Frye, M.A. Chahine, D.M. Cash, M.G. Barbe, B.S. Babel, M. Casper, T.J. Whitman, L.E. Lindler, R.A. Bowden and M.P. Nikolich. Genotypic and phenotypic correlations of multidrug-resistant *Acinetobacter baumannii-A. calcoaceticus* complex strains isolated from patients at the National Naval Medical Center. J. Clin. Micro. 2010 Nov; 48(11):4333-6. Epub 2010 Aug 25.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
The Walter Reed Army Institute of Research conducts research on bacterial threat agents, including the study of therapeutics against these agents.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category A and B Priority Pathogens
- **Overlap Select Agents**
  Including NIAID Category A and B Priority Pathogens

III. Outdoor Studies:
None

[*] Including viruses and prions.

Form A, Part 2 (iii)

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Brookhaven National Laboratory

2. Where is it located (provide both address and geographical location)?

Brookhaven National Laboratory
Biology Department
Upton, New York 11973-5000

3. Floor area of laboratory areas by containment level.

BL1 (sqM)	103
BL2 (sqM)	165
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	268

4. The organizational structure of each facility.

I Total Number of Personnel 15

II Division of Personnel:

Military	0
Civilian	15

III Division of Personnel by Category:

Scientists	10
Engineers	0
Technicians	5
Administrative/Support	0

IV List the scientific disciplines represented in the scientific/engineering support staff.

Biochemistry
Cell Biology
Epigenetics
Genomics

Microbiology
Molecular Biology
Protein crystallography
Virology
Protein Engineering
Protein Chemistry

V Are contractor staff working in the facility? If so, provide an approximate number.

No

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)
U.S. Department of Energy (DOE)
U.S. Department of Health and Human Services (HHS)
Internal (Laboratory Directed Research and Development LDRD)

VII What are the funding levels for the following program areas:

Research	$2,838,000
Development	$ 0
Test and evaluation	$ 0
Total	$2,838,000

VIII Briefly describe the publication policy of the facility:

It is the policy of Brookhaven National Laboratory that the results of research be published unless publication is expressly restricted by written agreement and that such publication is an essential part of the work of the Laboratory. The preparation of reviws, articles, monographs, etc., requested by sponsoring organizations and related to sponsored work, is considered part of the regular duties of the scientific and technical staff members. Scientists are required to publish their results in the peer reviewed scientific literature as well as present their work at national and international meetings.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Daegelen, P., Studier, F. W., Lenski, R. E., Cure, S., and Kim, J. F. Tracing ancestors and relatives of Escherichia coli B, and the derivation of B strains REL606 and BL21(DE3). Journal of Molecular Biology 394(4): 634-643 (December, 2009).

Jeong, H., Barbe, V., Lee, C. H., Vallenet, D., Yu, D. S., Choi, S.-H., Couloux, A., Lee, S.-W., Yoon, S. H., Cattolico, L., Hur, C.-G., Park, H.-S., Segurens, B., Kim, S. C., Oh, T. K., Lenski, R. E., Studier, F. W., Daegelen, P., and Kim, J. F. Genome sequences of Escherichia coli B strains REL606 and BL21(DE3). Journal of Molecular Biology 394(4): 644-652 (December, 2009).

Studier, F. W., Daegelen, P., Lenski, R. E., Maslov, S., and Kim, J. F. Understanding the differences between genome sequences of Escherichia coli B strains REL606 and BL21(DE3) and comparison of the E. coli B and K-12 genomes. Journal of Molecular Biology 394(4): 653-680 (December, 2009).

Janssen, P. J., Van Houdt, R., Moors, H., Monsieurs, P., Morin, N., Michaux, A., Benotmane, R., Leys, N., Vallaeys, T., Lapidus, A., Monchy, S., Taghavi, S., McCorkle, S., Dunn, J., van der Lelie, D., and Mergeay, M. The complete genome sequence of Cupriavidus metallidurans strain CH34, a master survivalist in harsh and anthropogenic environments. PLoS One 5(5): e10433 (May, 2010).

Mulligan, E., Hatchwell, E., McCorkle, S. R., and Dunn, J. J. Differential binding of Escherichia coli McrA protein to DNA sequences that contain the dinucleotide m5CpG. Nucleic Acids Research 38(6): 1997-2005 (April, 2010).

Appella, E. and Anderson, C. W. Dynamic protein interactions in complex networks. FEMS Journal 276(19): 5380 (October, 2009).

Meek, D. W. and Anderson, C. W. Posttranslational modification of p53: Cooperative integrators of function. Cold Spring Harbor Perspectives in Biology, Volume on The p53 Family, A. J. Levine and D. Lane, Editors, pp. 1-16, Cold Spring Harbor Laboratory Press, NY (December, 2009). [Featured Article]

Lebel, E. A., Boukamp, P., and Tafrov, S. T. Irradiation with heavy-ion particles changes the cellular distribution of human histone acetyltransferase HAT1. Molecular and Cellular Biochemistry 339(1-2): 271-284 (June, 2010).

Lai, B., Agarwal, R., Nelson, L. D., Swaminathan, S., and London, E. Low pH-induced pore formation by the T domain of Botulinum toxin type A is dependent upon NaCl concentration. Journal of Membrane Biology 236(2): 191-201 (July, 2010).

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:

The overall objective of the work is to develop countermeasures for biowarfare agents. The specific aim of the projects are to determine the three-dimensional structures of the agents.

[*] Including viruses and prions.

The purified agents are crystallized using standard crystallization techniques and brought to the National Synchrotron Light Sources (also at Brookhaven National Laboratory) for x-ray diffraction studies. These results can lead to vaccine development, treatment, and/or diagnosis.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category A Priority Pathogens
- **Other pathogens or toxins**

Work only involves one toxin (which is both a Select Agent Toxin and NIAID Category A Pathogen)

III. Outdoor Studies:
None

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Idaho National Laboratory

2. Where is it located (provide both address and geographical location)?

Idaho National Laboratory
2525 Fremont Ave.
Idaho Falls, Idaho 83415-2203

3. Floor area of laboratory areas by containment level.

BL1 (sqM)	75
BL2 (sqM)	15
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	90

4. The organizational structure of each facility.

I Total Number of Personnel 2

II Division of Personnel:

Military	0
Civilian	2

III Division of Personnel by Category:

Scientists	2
Engineers	0
Technicians	0
Administrative/Support	0

IV List the scientific disciplines represented in the scientific/engineering support staff.

Bioinformatics
Decontamination Efficacy Study
Microbiology
Molecular Biology

Wildlife Health

V Are contractor staff working in the facility? If so, provide an approximate number.

No

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of the Interior (DOI) – National Park Service

VII What are the funding levels for the following program areas:

Research	$ 0
Development	$20,000
Test and evaluation	$ 0
Total	$20,000

VIII Briefly describe the publication policy of the facility:

Publication of research results is encouraged but may be limited if guidance from a particular U.S. Government customer restricts free dissemination of results. Work for others is considered proprietary and only released with permission of the private entity funding the work.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

None

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
Independent testing of wildlife samples to confirm culture or other diagnostic tests for brucellosis; evaluation of decontamination technology for fungal toxins in grain.

II. Agents Microorganisms and/or Toxins:

- **Overlap Select Agents**

* Including viruses and prions.

Including NIAID Category B Priority Pathogens

- **Other pathogens or toxins**

  Including non-Select Agent, NIAID Category B Priority Pathogens

III. Outdoor Studies:

Wildlife disease testing supports U.S. Deptartment of Interior (National Park Service) activities. Toxin analysis supports private local industry developing grain treatment to remove naturally-occurring fungal toxin contamination. Laboratory space reported here reflects only that which supports biodefense-related activities.

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Lawrence Livermore National Laboratory

2. Where is it located (provide both address and geographical location)?

Lawrence Livermore National Laboratory
7000 East Avenue
Livermore, California 94550

3. Floor area of laboratory areas by containment level.

BL1 (sqM)	3278
BL2 (sqM)	1261
BL3 (sqM)	60
BL4 (sqM)	0
Total (sqM)	4599

4. The organizational structure of each facility.

I Total Number of Personnel 115

II Division of Personnel:

Military	0
Civilian	115

III Division of Personnel by Category:

Scientists	93
Engineers	8
Technicians	14
Administrative/Support	0

IV List the scientific disciplines represented in the scientific/engineering support staff.

Aerosol Science
Analytical Biochemistry
Bacteriology
Biochemistry
Bioengineering

Bioinformatics
Biology
Biophysics
Chemical Engineering
Chemistry
Computer Science
Environmental Science
Epidemiology
Immunology
Infectious Disease
Microbial Forensics
Microbiology
Microfluidics
Molecular Biology
Molecular Computational Biology
Nanotechnology
Pharmacology
Plant Biotechnology
Proteomics
Toxicology
Virology
Analytical Mass Spectrometry
Mass Spectrometry Biochemistry

V Are contractor staff working in the facility? If so, provide an approximate number.

No

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)
U.S. Department of Homeland Security (DHS)
Internal (Laboratory Directed Research and Development LDRD)
Other Governmental Agencies

VII What are the funding levels for the following program areas:

Research	$17,894,000
Development	$ 0
Test and evaluation	$ 553,000
Total	$18,447,000

VIII Briefly describe the publication policy of the facility:

Lawrence Livermore National Laboratory's (LLNL) publication policy is contained in the "LLNL Information Management Policy" (January 2008). Prior to publication, document content including scientific, technical and programmatic information is reviewed and released by the author's directorate, the Office of Classification and Export Control, and/or the Industrial Partnerships Office, as appropriate. Subject matter experts may also be required to review documents based on the content.

Every year, authors at LLNL create thousands of documents. These documents are widely varied in scientific, technical, programmatic, and administrative content and scope. Some documents are written for the scientific community outside the Laboratory and some are written for the general public. Some documents are written for a more limited audience.

Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following:

1) classification/declassification,
2) copyrighted materials or other intellectual property,
3) export controls or distribution restrictions, and
4) sensitive content that limits access.

The LLNL Information Management Policy ensures that unclassified and classified scientific and technical information resulting from LLNL research is identified, processed, disseminated, and preserved in accordance with our contract and DOE requirements.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

LLNL-POST-424889, Point-of-Care Diagnostics for FMDv, Jane P. Bearinger, LLNL.

LLNL-PRES-423583, Phagocytosis in Epithelial Cells; Mechanical Properties and the Dynamic Mechanical Response of Chondrocytes; Nanolipoprotein Particles: Update Craig Blanchette, LLNL.

LLNL-ABS-426374 Versatile delivery and immune-stimulatory platform, Craig Blanchette, LLNL; Nicholas Fischer, LLNL; Paul Hoeprich, LLNL, LDLR review, Washington D.C., United States.

LLNL-PRES-455697 Nanolipoprotein particles (NLPs) as a versatile platform for co-delivery of multiple adjuvants, N. O. Fischer, LLNL.

LLNL-PRES-456662 Nanolipoprotein particles (NLPs) as an immunostimulatory delivery vehicle for vaccine development against Brucella; C. D. Blanchette, LLNL.

LLNL-PRES-423230 "Nanolipoprotein Particles (NLPs): Versatile Biological Platforms for Biomolecular Delivery and Diagnostics, Nicholas O. Fischer, LLNL; Craig D. Blanchette,

LLNL; Paul D. Hoeprich.

LLNL LLNL-POST-446512 Yersinia pestis proteomics and vaccine development - poster, R. M. Paddack, LLNL; L. M. Evans, LLNL; S. T. Smiley, Trudeau Institute; B. A. Chromy.

LLNL LLNL-ABS-447593 Stability of NLPs at different temperatures and complex media, P. Venkataraman, LLNL; N. O. Fischer, LLNL; C. D. Blanchette, LLNL; Science Teacher and Researcher Closing Conference, Livermore, CA, United States.

LLNL-POST-444951 Stability of NLPs at different temperatures and complex media, P. Venkataraman, LLNL; N. O. Fischer, LLNL; C. D. Blanchette, LLNL.

LLNL-POST-447157, Multiple Drug Resistance in Ciprofloxacin and Doxycycline Resistant Avirulent Yesrinia Pestis L. Richards, LLNL; F. Bourguet, LLNL; L. Vergez, LLNL; P. Jackson, LLNL.

LLNL-POST-446079, Comparison of Lysis Efficiency for DNA Extraction of Spore-forming Bacillus thuringiensis, J. Dunkel, LLNL; M. Ramsey, LLNL; A. Erler, LLNL; L. Wogan, LLNL; W. Hoppes, LLNL.

LLNL-POST-446411, Protein-Protein Interactions in AI-2 Mediated Quorum Sensing in Yersinia pestis, N. Ho, Las Positas College, Livermore, CA; M. Stark., Kapolei High School, Kapolei, HI; M. Corzett, LLNL; B. Segelke., LLNL.

LLNL-POST-447996, Development of a Quantitative Mircoarray Fluidic Device, M. M. Arteaga, Hogan High School; J. Bearinger, LLNL; M. A. Coleman, LLNL.

LLNL-POST-447212, Dual Polarization Interferometry for Small Molecule Drug Development Against Francisella tularensis, S. Nawim, LLNL; L. M. Evans, LLNL; B. A. Chromy, LLNL.

LLNL-ABS-446433, Yersinia pestis proteomics and vaccine development, R. M. Paddack, California Polytechnic State University; L. M. Evans, LLNL; J. Lin, Trudeau Institute; S. T. Smiley, Trudeau Institute; B. A. Chromy, LLNL; Science Teacher and Researcher Closing Conference, Livermore, CA, United States.

LLNL-ABS-447391, Dual Polarization Interferometry for Small Molecule Drug Development Against Francisella tularensis, S. Nawim, LLNL; L. M. Evans, LLNL; B. A. Chromy, LLNL; Science Teacher and Researcher Closing Conference, Livermore, CA, United States.

LLNL-POST-433931, Acoustic focusing for high-throughput continuous-flow biological sample preparation, M. Shusteff, LLNL; D. A. Dehlinger, LLNL; K. A. Fisher, LLNL; D. A. Wajda, LLNL; R. P. Mariella, LLNL; K. A. Rose, LLNL.

LLNL-POST-447951, Cell Separation Using Acoustic Focusing For Automated Sample Preparation, M. S. Chinn, LLNL; M. Shusteff, LLNL; D. A. Dehlinger, LLNL; K. A. Rose, LLNL.

LLNL-POST-432926, Rapid Preparation of Biological Samples Using Microfluidic Technologies, D. A. Dehlinger, LLNL; K. A. Rose, LLNL; M. Shusteff, LLNL; E. Wheeler, LLNL; C. Carrillo, LLNL; K. Fisher, LLNL; C. Bailey, LLNL; R. P. Mariella, LLNL.

LLNL-PRES-428119, Microfluidic Virtual Filters for Automated Biological Sample Preparation, Klint A. Rose, LLNL LLNL-POST-424314, Rapid Analysis of Known and Unknown Pathogens Using a Pan-Microbial Detection Microarray, J. Thissen, LLNL; S. Gardner, LLNL; K. McLoughlin, LLNL; T. Slezak, LLNL; C. Jaing, LLNL.

LLNL-JRNL-426582, Metagenomics and pan-microbial array analyses of live attenuated viral vaccines for minority genetic variants and adventitious viruses. J.G. Victoria, LLNL; E.L. Delwart, LLNL; C. Wang, LLNL; M.S. Jones, LLNL; C. Jaing, LLNL; K. McLoughlin, LLNL; S. Gardner, LLNL; Journal of Virology.

LLNL-ABS-436534, Application of a Microbial Detection Array in biodefense and public health, C. Jaing, LLNL ; S. Gardner, LLNL; K. McLoughlin, LLNL; J. Thissen, LLNL; T. Slezak, LLNL; Chemical and Biological Defense S&T Conference, Orlando, FL, United States.

LLNL-POST-424313, Short Primers for Amplification of Diverse Virus Strains, C. Hara, LLNL; A. Hiddessen, LLNL; S. Gardner, LLNL; J. Olivas; C. Bailey, LLNL.

LLNL-POST-428331, Automated Sample Preparation for Biological Analysis, Chris Bailey, LLNL; Klint Rose, LLNL; Ray Mariella, LLNL; Maxim Shusteff, LLNL; Dietrich Dehlinger, LLNL; Reg Beer, LLNL; Elizabeth Wheeler, LLNL.

LLNL-BOOK-432731, Metabolism of Yersinia pestis, Ali Navid, LLNL; Eivind Almaas, Norwegian University of Science & Technoloy.

LLNL-JRNL-463445, Development and Initial Results of a Low Cost, Disposable, Point-of-Care Testing Device for Pathogen Detection, J. P. Bearinger, LLNL; L. C. Dugan, LLNL; B. R. Baker, LLNL; S. B. Hall, LLNL; K. Ebert, IAH, Pirbright, U.K.; V. Mioulet, IAH, Pirbright, U.K.; M. Madi, IAH, Pirbright, U.K.; D. P. King, IAH, Pirbright, U.K.; IEEE Transactions in Biomedical Engineering.

LLNL-PRES-428022, Nanolipoprotein Particles - Platform for Membrane Proteins and Vaccinies, Paul Hoeprich, LLNL.

LLNL-POST-427627, Speeding Medical Countermeasure Development with Accelerator Mass Spectrometry (AMS), Kenneth Turteltaub, LLNL.

LLNL-ABS-427357, Flexible and Rapid Therapeutic Countermeasures for Global Biosecurity, J. P. Bearinger, LLNL; LDRD Symposium, Washington, DC, United States.

LLNL-BOOK-425971, Design of Genomic Signatures of Pathogen Identification & Characterization, T. Slezak, LLNL; S. Gardner, LLNL; J. Allen, LLNL; E. Vitalis, LLNL; C. Jaing, LLNL; Microbial Forensics (2nd Edition).

LLNL-BR-425622, LLNL Microarrays for Pathogen Detection, Characterization, and Forensic Analysis, C. Jaing, LLNL; T. Slezak, LLNL; H. Franz, LLNL.

LLNL-ABS-462189, Application of genotyping, microarray and sequencing technologies to detect biothreat agents from complex environmental samples, C. Jaing, LLNL; J. Thissen, LLNL; J. Wollard, LLNL; A. Hinckley, LLNL; P. Jackson, LLNL; ASM Biodefense and Emerging Diseases Research Meeting, Washington DC, United States.

LLNL-POST-428245, Microarrays Rapidly Detect Bacterial and Viral Pathogens, C. Jaing, LLNL; S. Gardner, LLNL; K. McLoughlin, LLNL; J. Thissen, LLNL; T. Slezak, LLNL.

LLNL-ABS-422765, Identification and characterization of REP24, a novel Francisella tularensis cysteine protease. S. El-Etr, LLNL; M. Corzett, LLNL; K. Belhocine, Stanford; N.O Fischer, LLN ; A. Zemla, LLNL; C. Zhou, LLNL; D. Monack, Stanford; B.W. Segelke, LLNL; American Society for Microbiology, San Diego, CA, United States.

LLNL-PRES-461431, SNP Microarrays and combined phylogenetic analysis of array and sequence data, T. Slezak, LLNL.

LLNL-POST-429651, Structure-Based Drug Design for Medical Countermeasures, F. C. Lightstone, LLNL.

LLNL-PRES-423240, Point-of-Care Technology Update, J. M. Dzenitis, LLNL; B. R. Baker, LLNL; W. H. Benner, LLNL; L. C. Dugan, LLNL; S. B. Hall, LLNL; V. J. Riot, LLN ; W. J. Benett, LLNL; C. Torres, LLNL.

LLNL-POST-422923, "Loop-Mediated Isothermal Amplification (LAMP): A Rapid, Multi-Pathogen Detection Device for Staphylococcus aureus and Pseudomonas aeruginosa in Whole Blood, K. S. Hale, UC Davis; N. L. Gentile, UC Davis; B. R. Baker, LLNL; S. B. Hall, LLNL; E. A. Vitalis, LLNL; N. K. Tran, UC Davis; R. F. Louie, UC Davis; J. M. Dzenitis, LLNL; G. J. Kost, UC Davis.

LLNL-ABS-422924, Loop-Mediated Isothermal Amplification (LAMP): A Rapid, Multi-pathogen Detection Device for Staphylococcus aureus and Pseudomonas aeruginosa in Whole Blood, K. N. Hale, UC Davis; N. L. Gentile, UC Davis; B. R. Baker, LLNL; S. B. Hall, LLNL; E. A. Vitalis, LLNL; N. K. Tran, UC Davis; R. F. Louie, UC Davis; J. M. Dzenitis, LLNL; G. J. Kost, LLNL; AACC 42nd Annual Oak Ridge Conference, San Jose,

CA, United States.

LLNL-POST-460471, Understanding the Role of Quasispecies in Interspecies Transmission Events, M. K. Borucki, LLNL; J. E. Allen, LLNL; S. Messenger, Ca Dept Public Health; T. R. Slezak, LLNL.

LLNL-JRNL-426611, CHARACTERIZATION OF A NOVEL ENDOLYTIC PROTEIN, AMPD BCZK2532 AS A BACILLUS ANTHRACIS ANTIMICROBIAL PROTEIN, Feliza A. Bourguet, LLNL; Brian E. Souza, LLNL; Matthew A. Coleman, LLNL; Paul J. Jackson, LLNL; Applied and Environmental Microbiology.

LLNL-POST-447154, Mechanisms of Antibiotic Resistance in Burkholderia thailandensis, M. J. Pavlovich, LLNL; L. M. Vergez, LLNL; P. J. Jackson, LLNL.

LLNL-POST-429027, CHARACTERIZATION OF A NOVEL BACTERIAL PROTEIN ENCODED BY THE BACILLUS ANTHRACIS GENOME, Paul J. Jackson, LLNL.

LLNL-ABS-462892, Identification of SNPs Responsible for Antibiotic Resistance in Biothreat Agents by DNA Microarrays and Illumina Sequencing, J. Thissen, LLNL; C. Jaing, LLNL; L. Vergez, LLNL; F. Bourguet, LLNL; K. Mcloughlin, LLNL; S. Mabery, LLNL; P. J. Jackson, LLNL; ASM Biodefense and Emerging Diseases, Washington, DC, United States.

LLNL-POST-448536, Antibiotic Resistance Mutation Discovery Using Tiling Arrays and High-Throughput Sequencing, K. S. McLoughlin, LLNL; S. N. Gardner, LLNL; C. J. Jaing, LLNL; T. R. Slezak, LLNL.

LLNL-POST-447560, Applications of Microarrays: Identifying Viral Pathogens, S. S. D'Souza, Johns Hopkins University; J. B. Thissen, LLNL; S. L. Mabery, LLNL; K. S. McLoughlin, LLNL; S. N. Gardner, LLNL; T. Slezak, LLNL; C. J. Jaing, LLNL.

LLNL-ABS-436591, Antibiotic Resistance Mutation Discovery Using Tiling Microarrays and High-Throughput Sequencing, K. McLoughlin, LLNL; Chemical and Biological Defense S&T Conference, Orlando, FL, United States.

LLNL-BOOK-423503, Non-biological measurements on biological agents, Stephan P. Velsko, LLNL; Microbial Forensics 2nd Edition

LLNL-PROC-424924, NanoSIMS analysis of Bacillus spores for forensics, P. K. Weber, LLNL; M. L. Davisson, LLNL; S. P. Velsko, LLNL; Microscopy and Microanalysis, Portland, OR, United States.

LLNL-ABS-446059, Spore Dating Using the Carbon-14 Bomb Pulse, B. A. Buchholz, LLNL; J. A. Cappuccio, LLNL; M. J. Sarachine, LLNL; American Academy of Forensic

Sciences 63rd Annual Meeting, Chicago, IL, United States.

LLNL-PRES-451851, LLNL Microarray and Sequence Data Analysis for Pathogen Detection and Characterization, K. McLoughlin, LLNL.

LLNL-PRES-426269, Application of Microarrays for Rapid Characterization of Pathogens, S. Gardner, LLNL ; K. McLoughlin, LLNL; J. Allen, LLNL; T. Slezak, LLNL.

LLNL-PRES-452933, Forensic TaqMan and Microarray Assays for Viral Genotyping, C. Jaing, LLNL.

LLNL-POST-458473, saSNP Approach for Scalable SNP Analyses of 100+ Bacterial or Viral Genomes, S. Gardner, LLNL; T. Slezak, LLNL.

LLNL-PRES-452351, LLNL Pathogen Detection and Genotyping Array Designs, S. Gardner, LLNL.

LLNL-PRES-448771, Detection of Threat Agents from Complex Environmental Samples using Genotyping, Microarray and Sequencing Technologies C. Jaing, LLNL; P. Jackson, LLNL

LLNL-PRES-424151, Application of Microarrays for Rapid Detection and Subtyping of Pathogens, C. Jaing, LLNL.

LLNL-JRNL-451280, Forensic Inference on Infection Transmission Networks, J. J. Osburn, LLNL; J. E. Allen, LLNL; C. T. Cunningham, LLNL; S. P. Velsko, LLNL, Investigative Genetics.

LLNL-ABS-436432, Combining knowledge of viral evolution and epidemiology to identify the source of a viral outbreak. J. Allen, LLNL; Chemical and Biological Defense S&T Conference, Orlando, FL, United States LLNL-PRES-458191, Overview of CBRNE Countermeasures, D. J. Rakestraw, LLNL.

LLNL-POST-424263, Multiplexed Diagnostic Assays for Detection of High Consequence Foreign and Emerging Animal Disease, A. Carrillo, LLNL; K. Pitz, LLN ; J. Thissen, LLNL; J. Olivas, LLNL; B. Harrel, LLNL; M. El Sheikh, LLNL; M. Rasmussen, LLNL; R. Lenhoff, LLNL; P. Naraghi-Arani, LLNL.

LLNL-POST-423707, Navigating Dante's Inferno: Creation of Signatures for the Rapid Detection of Hemorrhagic Fever Agents, K. Pitz, LLNL; C. Carrillo, LLNL; J. Thissen, LLNL; J. Olivas, LLNL; B. Harrel, LLNL; M. El Sheikh, LLNL; R. Lenhoff, LLNL; P. Naraghi-Arani, LLNL.

LLNL-PRES-434076, Point-of-care diagnostic for FMDV, P. Naraghi-Arani, LLNL; J.

Bearinger, LLNL; L. Dugan, LLNL; B. Baker; S. Hall, LLNL.

LLNL-POST-423234, Identification of Novel MicroRNA Biomarkers of Viral Infection, P. Naraghi-Arani, LLNL; S. Gardner, LLNL; C. Jaing, LLNL; S. Bavari, LLNL.

LLNL-JRNL-423969, Decontamination Options for Drinking Water Contaminated with Bacillus anthracis Spores, E. Raber, LLNL; A. Burklund, The Athenian School; Applied and Environmental Microbiology.

LLNL-PRES-428211, Chemical, Biological and Explosives Countermeasures Program, David J. Rakestraw, LLNL.

LLNL-ABS-424156 2010 US EPA Decontamination Research and Development Conference Abstracts, R. Greenwalt, LLNL; C. Campbell, LLNL; B. Hoppes, LLNL; D. MacQueen, LLNL; 2010 US EPA Decontamination Research and Development Conference, Durham, NC, United States.

LLNL-PROC-426110, In vitro High-Resolution Architecture and Structural Dynamics of Bacterial Systems, A.J. Malkin, LLNL; PHysCell2009, Primosten, Croatia.

LLNL-POST-461525, Application of a Lawrence Livermore Microbial Detection Array (LLMDA) in Biodefense and Public Health C. Jaing, LLNL; J. Thissen, LLNL; S. Gardner, LLNL; K. McLoughlin, LLNL; T. Slezak, LLNL.

LLNL-POST-459198, Combining Knowledge of Viral Evolution and Epidemiology to Identify the Source of a Viral Outbreak, J. Allen, LLNL; S. Velsko, LLNL; J. Osburne, LLNL; K. Kim, LLNL; M. Pitluck, LLNL.

LLNL-PRES-464103, Microarrays, B. Panigrahi, LLNL.

LLNL-ABS-439760, Disposable Point of Care Diagnostics for Infectious Disease, J. Bearinger, LLNL; L. Dugan, LLNL; B. Baker, LLNL; S. Hall, LLNL; Chemical and Biological Defense Science and Technology Conference, Orlando, FL, United States

LLNL-POST-428146, LLNL's Role in the Department of Homeland Security BioWatch Program, Bunt, Thomas, LLNL.

LLNL-PRES-450591, Critical Reagent Program Assay Evaluation for BioWatch, L. Wogan, LLNL.

LLNL-PRES-425084, Single Cell Environmental Microbiology with Nano Secondary Ion Mass Spectrometry, J. Pett-Ridge, LLNL; P.K. Weber, LLNL.

LLNL-ABS-425706, Single Cell Environmental Microbiology with Nano Secondary Ion

Mass Spectrometry, J. Pett-Ridge, LLNL; P.K. Weber, LLNL.

LLNL-ABS-424226, Stable Isotope Probing of RNA combining phylogenetic microarrays and high resolution secondary ion mass spectrometry to link composition and function in microbial systems, Xavier Mayali, LLNL; Peter K. Weber, LLNL; Eoin Brodie, Lawrence Berkeley National Laboratory; Shalini Mabery, LLNL; Paul Hoeprich, LLNL; Ian Hutcheon, LLNL; Jennifer Pett-Ridge, LLNL; Microscopy and Microanalysis, Portland, OR, United States.

LLNL-JRNL-427462, Structure-Function of Y. pestis LsrG, a Protein Involved in AI-2 Quorum Sensing, Brent Segelke, LLNL; marianne S. de Carvalho-Kavanagh, LLNL; Johana Schafer, LLNL; Julio Camarero, LLNL; Richard Law, LLNL ; Matthew A. Coleman, LLNL; Tim Lekin, LLNL; Victoria Lao, LLNL; Patrick Chain, LLNL; Vladimir Motin, LLNL; Emilio Garcia, LLNL; Adam Zemla, LLNL; Structure-Function of Y. pestis LsrG, a Protein Involved in AI-2 Quorum Sensing.

LLNL-POST-426102, Nanolipoprotein particles (NLPs) as a platform for synthetic cellulosomes, Craig Blanchette, LLNL; Michael Thelen, LLNL; Craig Blanchette, LLNL; Michael Thelen, LLNL

LLNL-POST-427525, Rapid Viability Polymerase Chain Reaction Method for Detection of virulent Bacillus anthracis from Environmental Samples, Sonia Letant, LLNL; Gloria Murphy, LLNL; Teneile Alfaro, LLNL; Julie Avila, LLNL; Victoria Lao, LLNL; Staci Kane, LLNL; Thomas Bunt, LLNL; Sanjiv Shah, EPA.

LLNL-POST-423231, Rapid Viability Polymerase Chain Reaction Method for Detection of Biological Select Agents from Environmental Samples, S. Letant, LLNL; G. Murphy, LLNL; T. Alfaro, LLNL; J. Avila, LLNL; V. Lao, LLNL; S. Kane, LLNL; T. Bunt, LLNL; O. Vincent, EPA; S. Shah, EPA.

LLNL-PRES-422287, Rapid Viability Polymerase Chain Reaction Method for Detection of Biological Select Agents from Environmental Samples, S. Letant, LLNL; G. Murphy, LLNL; T. Alfaro, LLNL; J. Avila, LLNL; V. Lao, LLNL; S. Kane, LLNL; T. Bunt, LLNL; O. Vincent, EPA; S. Shah, EPA.

LLNL-POST-425732, Rapid Viability Polymerase Chain Reaction (RV-PCR) methods for Detection of Bacillus Anthracis, Yersinia pestis and Francisella tularensis from Environmental Samples, Gloria Murphy, LLNL; Victoria Lao, LLNL; Teneile Alfaro, LLNL; Staci Kane, LLNL; Thomas Bunt, LLNL; Sanjiv Shah, EPA; Sonia Letant, LLNL.

LLNL-JRNL-448773, Rapid Viability Polymerase Chain Reaction Method for Detection of virulent Bacillus anthracis from Environmental Samples, S. Letant, LLNL; G. Murphy, LLNL; T. Alfaro, LLNL; J. Avila, LLNL; S. Kane, LLNL; E. Raber, LLNL; T. Bunt, LLNL; S. Shah, US EPA; Applied Environmental Microbiology.

LLNL-ABS-453492, Rapid Viability PCR Method for Viable Anthrax Spores Detection During the Restoration Phase of a Bioterrorism Event, S. Letant, LLNL; G. Murphy, LLNL; T. Alfaro, LLNL; V. Lao, LLNL; S. Kane, LLNL; T. Bunt, LLNL; S. Shah, US EPA; 4th National Conference on Environmenatl Sampling and Detection of Bio-Threat Agents, New Orleans, LA, United States.

LLNL-ABS-425277, Rapid Viability Polymerase Chain Reaction (RV-PCR) protocols for Bacillus Anthracis, Yersinia pestis and Francisella tularensis, G. Murphy, LLNL; V. Lao, LLNL; T. Alfaro, LLNL; S. Kane, LLNL; T. Bunt, LLNL; S. Shah, EPA; S. Letant, LLNL; NCASM Spring Meeting, Pleasanton, CA, United States

LLNL-PRES-463812, Breath Analysis for National Security Applications: Emerging Biometrics and Forensics, G. Farquar, LLNL; M. Frank, LLNL.

LLNL-POST-458672, Bio-threat Simulants Produced with Food Additives and DNA for the Testing of Biodetector Networks, R. N. Udey, LLNL; C. A. Hara, LLNL; E. D. Wheeler, LLNL; C. B. Thomas, LLNL; A. D. Jones, Michigan State University; G. R. Farquar, LLNL.

LLNL-PRES-429116, Bio-threat Simulants produced with FDA food additives containing DNA for the testing of bio-detector networks, George Farquar, LLNL.

LLNL-POST-463657, Detection of Francisella tularensis Volatile Emissions by Solid-Phase Microextraction and Gas Chromatography-Mass Spectrometry, R. N. Udey, LLNL; A. M. Williams, LLNL; G. R. Farquar, LLNL; A. Rasley, LLNL; M. Frank, LLNL.

LLNL-POST-448732, Detection of Francisella tularensis Volatile Emissions During Infection of Human Monocytes by Solid-Phase Microextraction and Gas Chromatography-Mass Spectrometry, J. S. Reich, LLNL; A. S. Mostaghim, LLNL; D. J. Kennedy, LLNL; A. Lin, LLNL; R. N. Udey, LLNL; A. M. Williams, LLNL; G. R. Farquar, LLNL; A. Rasley, LLNL; M. Frank, LLNL.

LLNL-PRES-433974, Bio-threat Simulants produced with FDA food additives containing DNA for the testing of bio-detector networks, G. Farquar, LLNL.

LLNL-ABS-436371, Automated Microarray Screening for Detection of Emerging Biological Threats, E. K. Wheeler, LLNL; J. R. Deotte, LLNL; C. A. Hara, LLNL; S. L. Mabery, LLNL; N. R. Beer, LLNL; J. M. Dzenitis, LLNL; 2010 Chemical and Biological Defense Science and Technology, Orlando, FL, United States.

LLNL-BOOK-426687, Genomic identification of regulatory elements by evolutionary sequence comparison and functional analysis, G. G. Loots, LLNL, Adv Genet. LLNL-WEB-462047, Lab finds crystal clear way to better biodection, C. Hartmann-Siantar, LLNL.

LLNL-WEB-462032, Mother-daughter research pool cleans up anthrax, C. Hartmann-

Siantar, LLNL.

LLNL-WEB-451592, New device quickly detects array of biohazards, C. Hartmann-Siantar, LLNL.

LLNL-WEB-458212, Microbial Detection Array Wins FLC Tech Transfer Award, C. Hartmann-Siantar, LLNL.

LLNL-POST-439731, A multidisciplinary approach to predicting ivral emergence, M. Borucki, LLNL; J. Allen, LLNL; A. Zemla, LLNL; C. Zhou, LLNL; S. Messenger, LLNL; F. Balagadde, LLNL; K. Rose, LLNL; S. Gardner, LLNL; T. Slezak, LLNL; H. Franz, LLNL

LLNL-PRES-463634, Systems Studies of CBRN Threats and Countermeasures, T. Edmunds, LLNL; R. Wheeler, LLNL.

LLNL-PRES-459113, Characterization of Burkholderia isolates using genotyping microarrays, C. Jaing, LLNL

LLNL-PRES-436820, Micro/Nano-Technology at LLNL, N. R. Beer, LLNL LLNL-PRES-460631, Chicken soup for the spore, L. Dugan, LLNL

LLNL-ABS-462185, Rapid Viability Methods for BioThreat Agents on Surface and Environmental Samples: DNA- and RNA-based Approaches, S. Letant, LLNL; S. Kane, LLNL; G. Murphy, LLNL; V. Lao, LLNL; T. Alfaro, LLNL; T. Bunt, LLNL; Rapid, New Orleans, LA, United States.

LLNL-PRES-458078, Nickel-Chelating Nanolipoprotein Particles (NiNLPs) as Versatile Platforms for Vaccine Development, N. O. Fischer, LLNL; C. B. Blanchette, LLNL; P. W. Mason, UTMB; P. D. Hoeprich, LLNL.

LLNL-POST-452651, Early and Rapid Detection of Ebola Hemorrhagic Fever Virus, A. Rosa, LLNL; C. Carrillo, LLNL; J. Thissen, LLNL; J. Olivas, LLNL; M. El Sheikh, LLNL; R. Lenhoff, LLNL; P. Naraghi-Arani, LLNL.

LLNL-ABS-463076, Detection of Intentional Food Contamination: Multiplexed Diagnostic Assays Applied to the Detection of Bio-threat Agents in Complex Matrices, A. Carrillo, LLNL; J. Olivas, LLNL; M. El Sheikh, LLNL; A. Rosa, LLNL; R. Lenhoff, LLNL; P. Naraghi-Arani, LLNL; ASM Biodefense and Emerging Diseases Research Meeting, Washington, DC, United States.

LLNL-ABS-422483, Differential Endosomal Trafficking of Pathogenic and Non-pathogenic Strains of Francisella tularensis in Human Dendritic Cells, L. Vergez, LLNL; A. Rasley, LLNL; S. El-Etr, LLNL; American Society for Microbiology, San Diego, CA, United States.

LLNL-ABS-425003, Francisella tularensis Type A Strains Preferentially Replicate in Human Monocytes and Induce Marked Secretion of inflammatory Chemokines, S. El-Etr, LLNL; San Francisco, CA, United States.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
LLNL is performing work in the area of biological agent detection, therapeutics development, virulence mechanism elucidation, structural characterization, agent viability testing, response planning, restoration, and forensics.

The biological detection platforms being developed at LLNL include multiplex assays, the Autonomous Pathogen Detection System (APDS), Biological Aerosol Mass Spectrometry (BAMS), Enhanced Biological Aerosol Detection System (EDBADS), and the Viral Discovery Platform (VDP). These platforms use PCR, immunoassay, mass spectrometry and genomic sequencing to gather useful information about the biological species present in the sampling environment. LLNL is also working to support and upgrade the biological detection network put in place by DHS which is known as BioWatch. Personnel from LLNL play an important role in the bioinformatics required to develop new detection assays for the various detection platforms. The development and screening of new DNA/RNA based assays is also a core area of expertise at LLNL. Testing and validation of new hardware components, and training for the BioWatch network is another area where LNL supports the DHS mission.

In addition to the detection platforms LLNL is also working on tools that will help to restore normal activities in the event that a biological agent is used. These include developing rapid viability testing, decontamination strategies, and biological response plans for DHS, DOD, and EPA. We also have substantial activities in developing forensic assays to help determine where an agent may have come from and who might be responsible for the use of that agent.

Beyond detection, response, recovery, and attribution, LLNL also has ongoing research projects to help elucidate the mechanism of host-pathogen interactions. The goal of this research is to understand how an organism is able to defeat or circumvent the host immune system. This will enable the development of new intervention strategies that are specifically targeted to steps in the organism life cycle. LLNL is also involved in the search for new compounds that can be used as effective intervention strategies as well as the development of novel vaccine strategies for disease prevention. This work involves stimulating either innate or adaptive immunity for the prophylaxis and therapeutics.

* Including viruses and prions.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category A and B Priority Pathogens
- **Overlap Select Agents**
  Including NIAID Category A and B Priority Pathogens
- **Other pathogens or toxins**
  Including non-Select Agent, NIAID Category A, B and C Priority Pathogens

All Select Agent Toxin(s) below the *de minimus* level and thus exempt from registration with the Select Agent Program.

III. Outdoor Studies:
None

Form A, Part 2 (iii)

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Los Alamos National Laboratory

2. Where is it located (provide both address and geographical location)?

P. O. Box 1663
Los Alamos, New Mexico 87545

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	444
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	444

4. The organizational structure of each facility.

I Total Number of Personnel 84

II Division of Personnel:

Military	0
Civilian	84

III Division of Personnel by Category:

Scientists	48
Engineers	4
Technicians	32
Administrative/Support	0

IV List the scientific disciplines represented in the scientific/engineering support staff.

Analytical Biochemistry
Bacteriology
Biochemistry
Bioengineering
Bioinformatics
Biology

Biology Engineering
Biotechnology
Cell Biology
Ecology
Epidemiology
Genomics
High throughput sequencing
Immunology
Infectious Disease
Microbial Forensics
Microbiology
Molecular Biology
Molecular Computational Biology
Pharmacology
Plant Biotechnology
Plant Molecular Biology
Plant Pathology
Plant Virology
Scale-up and Process Automation.
Structural Biology
Virology

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 2

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)
U.S. Department of Health and Human Services (HHS)
U.S. Department of Homeland Security (DHS)
Internal (Laboratory Directed Research and Development LDRD)
Other Governmental Agencies

VII What are the funding levels for the following program areas:

Research	$12,382,000
Development	$ 2,890,000
Test and evaluation	$ 84,000
Total	$15,356,000

VIII Briefly describe the publication policy of the facility:

As a U.S. Department of Energy/National Nuclear Security Administration (DOE/NNSA) facility, Los Alamos National Laboratory (LANL) is required to make scientific and technical information broadly available, within applicable laws and Departmental requirements, to accomplish mission objectives and strategic goals, promote scientific advancement, satisfy statutory dissemination requirements, and ensure a fair return on Departmental and taxpayer investment.

The Laboratory has a mandate to ensure that scientific and technical information is identified, processed, disseminated, and preserved to enable the scientific community and the public to locate and use the unclassified and unlimited-distribution information resulting from DOE research and related endeavors. The Laboratory also has procedures in place to manage and protect classified, sensitive controlled unclassified, and export-controlled scientific and technical information, yet make it accessible for appropriate access by the Department, its contractors, and others.

Reviews are conducted prior to publication to determine availability of information, or restrictions thereto. These reviews include, but are not limited to, the following: 1) classification/declassification, 2) copyrighted materials or other intellectual property, 3) export controls or distribution restrictions, and 4) sensitive content that limits access.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Helen Cui, Tracy Erkkila, Lance Green, Cheryl Gleasner, Jennifer Harris, Chris Detter, (2010) High Throughput Laboratory Network: An Application of High Throughput Sequencing and Analysis, 5th Sequencing, Finishing, and Analysis in the Future Conference, June 2-4, 2010, Santa Fe, NM

Armand E. Dichosa, Michael S. Fitzsimons, Lea Weston, Xiaojing Zhang, and Cliff Han. Single cell genomics with artificial polyploidy. 2010 CBD S&T Conference, November15-19, 2010. Orlando, FL.

Grim CJ, Hasan NA, Taviani E, Haley B, Chun J, Brettin TS, Bruce DC, Detter JC, Han CS,Chertkov O, Challacombe J, Huq A, Nair GB, Colwell RR. (2010) Genome sequence of hybrid V.cholerae O1 MJ-1236, B-33 and CIRS101 and comparative genomics with V. cholerae. J Bacteriol. Mar 26.

Haley BJ, Grim CJ, Hasan NA, Choi SY, Chun J, Brettin TS, Bruce DC, Challacombe JF, Detter JC, Han CS, Huq A, Colwell RR. (2010) Comparative genomic analysis reveals evidence of two novel Vibrio species closely related to V. cholerae. BMC Microbiol. May 27;10(1):154.

Cliff S. Han, Lucy (Xiaojing) Zhang, Karen W. Davenport, Hajnalka E. Daligault, Olga Chertkov, Chris Munk, and John C. Detter. General Finishing Process with Second-

Generation Sequencing Technologies. 2010 CBD S&T Conference.

Hasan NA, Grim CJ, Haley BJ, Chun J, Alam M, Taviani E, Hoq M, Munk AC, Saunders E, Brettin TS, Bruce DC, Challacombe JF, Detter JC, Han CS, Xie G, Nair GB, Huq A, Colwell RR. (2010) Comparative genomics of clinical and environmental Vibrio mimicus. Proc Natl Acad Sci U S A. 107(49):21134-9

Hong-Geller, E and Micheva-Viteva, S. (2010) Functional gene discovery using RNA interference-based genomic screens to combat pathogen infection. Curr Drug Disc Tech. 7: 86-94.

Hong-Geller, E., Valdez, Y., Shou, Y., Yoshida, T., Marrone, B., and Dunbar, J. (2010) Evaluation of B. anthracis and Y. pestis sample collection from nonporous surfaces by quantitative real-time PCR. 50:431-7

Nileena Velappan, Hugh E. Fisher, Emanuele Pesavento, Leslie Chasteen, Sara D'Angelo, Csaba Kiss, Michelle Longmire, Peter Pavlik and Andrew R. M. Bradbury*, A comprehensive analysis of filamentous phage display vectors for cytoplasmic proteins: an analysis with different fluorescent proteins, Nucleic Acids Res 38, e22, (2010).

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:

The biological defense research at the Los Alamos National Laboratory includes the following areas: pathogen signature identification, host-pathogen interactions, biothreat agent virulence study, and pathogen detection technology development.

The main objectives for these research and development activities are to:

- study molecular, chemical, and physical signatures of biothreat agents for pathogen detection and characterization;
- study microbial organism genetic variations for detection assay design and improvement;
- evaluate detection assay and platform performance; improve sample collection techniques;
- develop environmental sample analysis and pathogen fate analysis techniques;
- develop DNA, RNA and protein based detection and bioforensics assays;
- develop next generation high throughput microbial sequencing and finishing capabilities;
- develop high throughput assays for host-pathogen protein interactions screening; and
- identify host molecular targets as potential therapeutic candidates.

[*] Including viruses and prions.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category A, B and C Priority Pathogens
- **Overlap Select Agents**
  Including NIAID Category A, B and C Priority Pathogens
- **USDA Select Agents and Toxins**
  Including NIAID Category B Priority Pathogens
- **USDA PPQ Select Agents and Toxins**
- **Other pathogens or toxins**
  Including non-Select Agent, NIAID Category A, B and C Priority Pathogens

All Select Agent Toxin(s) below the *de minimus* level and thus exempt from registration with the Select Agent Program.

III. Outdoor Studies:
None

Form A, Part 2 (iii)

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Pacific Northwest National Laboratory

2. Where is it located (provide both address and geographical location)?

P. O. Box 999
Richland, Washington 99352

3. Floor area of laboratory areas by containment level.

BL1 (sqM)	805
BL2 (sqM)	633
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	1438

4. The organizational structure of each facility.

I Total Number of Personnel 40

II Division of Personnel:

Military	0
Civilian	40

III Division of Personnel by Category:

Scientists	37
Engineers	0
Technicians	0
Administrative/Support	3

IV List the scientific disciplines represented in the scientific/engineering support staff.

Analytical Biochemistry
Analytical Chemistry
Bacteriology
Biochemistry
Bioenvironmental Engineering

Bioinformatics
Biophysics
Biotechnology
Cell Biology
Chemistry
Engineering
Environmental Engineering
Environmental Science
Food and Water Testing
Genomics
Infectious Disease
Mass Spectrometry
Mass Spectrometry Biochemistry
Microbial Forensics
Microbiology
Molecular Biology
Parasitology
Pathogenesis
Proteomics
Public Health
Structural Biology
Virology

V Are contractor staff working in the facility? If so, provide an approximate number.

No

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)
U.S. Department of Energy (DOE)
U.S. Department of Health and Human Services (HHS)
U.S. Department of Homeland Security (DHS)
U.S. Environmental Protection Agency (EPA)
Internal (Laboratory Directed Research and Development LDRD)

VII What are the funding levels for the following program areas:

Research	$8,070,000
Development	$ 0
Test and evaluation	$ 0
Total	$8,070,000

VIII Briefly describe the publication policy of the facility:

Pacific Northwest National Laboratory (PNNL) staff are encouraged to publish the results of their work in the peer-reviewed scientific literature. Prior to being released from the laboratory, each document must undergo internal peer-review, review by a technical editor and line management to assure that the document is well-written and contains original material. In addition, each document is checked to make sure it contains no information that could affect national security or information that might require intellectual property protection or an export control license.

The information release process is not required for proposals, internal communications or for speeches and publications unrelated to PNNL or its clients. A publication grid is available to help authors determine if a product needs to go through ERICA.

ERICA, an acronym for "Electronic Records and Information Capture Architecture" is PNNL's online system that:

- automates and tracks the Information Release process from the time that an information release form is initiated, through approvals, to the point of publication/external release;
- assigns an Information Release number to each product;
- captures information about what is being released outside PNNL (to clients or to the public) by PNNL authors;
- makes this information available, when appropriate, to the PNNL external publications web site and to DOE's Office of Scientific and Technical Information (OSTI);
- Makes this information available, when appropriate, to Laboratory users for SDRs, Annual Reports, bibliometric analysis, etc.

Reviewers include, but are not limited to, subject-matter experts, clients, and intellectual property experts, as well as Authorized Derivative Classifiers who determine if the product might contain national security or business sensitive information requiring classification or modification.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

A top-down LC-FTICR MS-based strategy for characterizing oxidized calmodulin in activated macrophages. Lourette N, Smallwood H, Wu S, Robinson EW, Squier TC, Smith RD, Pasa-Tolić L. J Am Soc Mass Spectrom. 2010 Jun; 21(6):930-9. Epub 2010 Mar 22. PMID: 20417115

Identification of methionine sulfoxide diastereomers in immunoglobulin gamma antibodies using methionine sulfoxide reductase enzymes. Khor HK, Jacoby ME, Squier TC, Chu GC,

Chelius D. MAbs. 2010 May; 2(3):299-308. Epub 2010 May 11

Straub TM, RA Bartholomew, CO Valdez, NB Valentine, A Dohnalkova, RM Ozanich, CJ Bruckner-Lea, and DR Call. 2010. "Human Norovirus Infection of Caco-2 Cells Grown as a 3-Dimensional Tissue Structure." Journal of Water and Health. doi:10.2166/wh.2010.106 Online ahead of print.

Ozanich RM, TM Straub, RA Bartholomew, L Zhang, NB Valentine, BM Cox, M Beganovic, and CJ Bruckner-Lea. 2010. "Listeria monocytogenes: Detection in a Day? Research towards an 8-Hr. Assay." Presented by Rich Ozanich (Invited Speaker) at The Northwest Food Manufacturing & Packaging Expo, Portland, OR on January 19, 2010.

PNWD-SA-8833. Ozanich RM, TM Straub, RA Bartholomew, L Zhang, NB Valentine, BM Cox, M Beganovic, and CJ Bruckner-Lea. 2010. "Development of a Rapid Method for Trace Detection of Listeria monocytogenes: Status Report." Presented by Rich Ozanich (Invited Speaker) at Northwest Food Processors Association Expo, Portland, OR on January 19, 2010.

PNWD-SA-8836. Straub TM, RA Bartholomew, NB Valentine, A Dohnalkova, CJ Bruckner-Lea, and DR Call. 2010. "Human Norovirus Replication in Tissue Culture." Presented by Timothy Straub (Invited Speaker) at International Symposium on Waterborne Pathogens, Manhattan Beach, CA on May 2, 2010.

PNWD-SA-8894. Straub TM, CO Valdez, NB Valentine, L Zhang, LA McCue, SC Wunschel, TM Mercier, N Doggett, J Gans, M Henrie, PK Dighe, TE Macdonald, DT Newby, M Walton, A Loftis, and RA Bartholomew. 2010. "Single and Multi-Laboratory Evaluation of TaqMan Real-Time PCR Assays for Discrimination of Francisella spp. Isolates." Presented by Timothy Straub (Invited Speaker) at DHS Performers Meeting, Washington, DC on August 16, 2010.

PNNL-SA-74521. Bartholomew RA, CL Baird, KD Victry, HE Engelmann, WB Chrisler, and TM Straub. 2010. "BioAssays - Near Term: Evaluation of Nucleic Acid and Immunoassays for DHS-Directed Targets." Presented by Rachel Bartholomew and Tim Straub (Invited Speaker) at DHS Performers Meeting, Washington, DC on August 16, 2010.

PNNL-SA-74558. Bartholomew RA, TM Straub, NB Valentine, L Zhang, A Dohnalkova, RM Ozanich, CJ Bruckner-Lea, and DR Call. 2010. "Use of a 3-D Cell Culture Model to Investigate Pathogenicity of Biological Agents of Concern to Assess "How Clean is Clean?"." Presented by Rachel Bartholomew (Invited Speaker) at Chemical and Biological Defense Science and Technology Conference, Orlando, FL on November 16, 2010.

PNWD-SA-9141. Straub TM, RA Bartholomew, NB Valentine, and CJ Bruckner-Lea. 2010. "Measuring Infectious Microbes Using Molecular Assays." Abstract submitted to American Water Works Association Annual Conference and Exposition, Chicago, IL.

PNWD-SA-8886. Presented to the AWWA annual conference June 21, 2010. Soares TA, CB Boschek, DO Apiyo, CL Baird, and TP Straatsma. 2010. "Molecular basis of the structural stability of a Top7-based scaffold at extreme pH and temperature conditions." Journal of Molecular Graphics and Modelling 28(8):755-765. doi:10.1016/j.jmgm.2010.01.013

Gray S, KM Weigel, KD Miller, J Ndung'u, P Buscher, TN Tran, CL Baird, and GA Cangelosi. 2010. "Flow cytometry-based methods for assessing soluble scFv activities and detecting pathogen antigens in solution." Biotechnology and Bioengineering 105(5):973-981.

Baird CL, CB Boschek, GW Buchko, and KD Victry. 2010. "Engineering ultra-stable affinity reagents using the protein Top7 as a scaffold." Presented by Cheryl Baird (Invited Speaker) at The 24th Annual Protein Society Symposium, San Diego, CA on August 1, 2010.

PNNL-SA-75568. 2010 Detection of Acetone Processing of Castor Bean Mash for Forensic Investigation of Ricin Preparation Methods Kreuzer-Martin HW, JH Wahl, CN Metoyer, HA Colburn, and KL Wahl. 2010. "Detection of Acetone Processing of Castor Bean Mash for Forensic Investigation of Ricin Preparation Methods." Journal of Forensic Sciences 55(4):908-914.

Residual Agar Determination in Bacterial Spores by Electrospray Ionization Mass Spectrometry Wahl KL, HA Colburn, DS Wunschel, CE Petersen, KH Jarman, and NB Valentine. 2010. "Residual Agar Determination in Bacterial Spores by Electrospray Ionization Mass Spectrometry." Analytical Chemistry 82(4):1200-1206.

Investigating Solvent Purity Utilizing Comprehensive Gas Chromatography: A Study of Acetones Wahl JH, CDH Bolz, and KL Wahl. 2010. "Investigating Solvent Purity Utilizing Comprehensive Gas Chromatography: A Study of Acetones." LC-GC Europe 23(4):188-199.

Analysis of Carbohydrate and Fatty Acid Marker Abundance in Ricin Toxin Preparations for Forensic Information Colburn HA, DS Wunschel, HW Kreuzer-Martin, JJ Moran, KC Antolick, and AM Melville. 2010. "Analysis of Carbohydrate and Fatty Acid Marker Abundance in Ricin Toxin Preparations for Forensic Information." Analytical Chemistry 82(14):6040-6047.

An efficient data format for mass spectrometry based proteomics Shah AR, JL Davidson, ME Monroe, AM Mayampurath, WF Danielson, III, Y Shi, AC Robinson, BH Clowers, ME Belov, GA Anderson, and RD Smith. 2010. "An efficient data format for mass spectrometry based proteomics." Journal of the American Society for Mass Spectrometry 21(10):1784-1788. doi:10.1016/j.jasms.2010.06.014.

Signature-Discovery Approach for Sample Matching of a Nerve-Agent Precursor using

Liquid Chromatography-Mass Spectrometry, XCMS, and Chemometrics Fraga CG, BH Clowers, RJ Moore, and EM Zink. 2010. "Signature-Discovery Approach for Sample Matching of a Nerve-Agent Precursor using Liquid Chromatography-Mass Spectrometry, XCMS, and Chemometrics." Analytical Chemistry 82(10):4165-4173.

Niemann GS, Brown RN, Gustin JK, Stufkens A, Shaikh-Kidwai AS, Li J, McDermott JE, Brewer HM, Schepmoes A, Smith RD, Adkins JN, Heffron F. Discovery of novel secreted virulence factors from Salmonella enterica serovar Typhimurium by proteomic analysis of culture supernatants. Infect Immun. 2011 Jan; 79(1):33-43. Epub 2010 Oct 25. PubMed PMID: 20974834; PubMed Central PMCID: PMC3019877.

McDermott JE, Corrigan A, Peterson E, Oehmen C, Niemann G, Cambronne ED, Sharp D, Adkins JN, Samudrala R, Heffron F. Computational prediction of type III and IV secreted effectors in gram-negative bacteria. Infect Immun. 2011 Jan; 79(1):23-32. Epub 2010 Oct 25. Review. PubMed PMID: 20974833; PubMed Central PMCID: PMC3019878.

Buchko GW, Niemann G, Baker ES, Belov ME, Smith RD, Heffron F, Adkins JN, McDermott JE. A multi-pronged search for a common structural motif in the secretion signal of Salmonella enterica serovar Typhimurium type III effector proteins. Mol Biosyst. 2010 Dec 8;6(12):2448-58. Epub 2010 Sep 29. PubMed PMID: 20877914.

Adkins JN, Mottaz H, Metz TO, Ansong C, Manes NP, Smith RD, Heffron F. Performing comparative peptidomics analyses of Salmonella from different growth conditions. Methods Mol Biol. 2010; 615:13-27. PubMed PMID: 20013197.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:

Our goal is to develop the means to rapidly create new affinity reagents that recognize entire families of threat agents, focusing on the development of reagents to detect certain isotoxins.

Affinity reagents that recognize a toxin family will provide an ability to monitor the presence of unexpected and evolved agents. Our approach will build on a naturally occurring protein scaffold (i.e., calmodulin) whose molecular plasticity permits binding to more than 300 different binding sequences with little sequence similarity. As current computational algorithms do not rationalize binding to these different structural motifs in a manner that effectively predicts additional binding partners present in cells, we propose to first identify the fundamental principles that permit rapid and high-affinity binding to target proteins. Using these insights, we will design and express high-affinity scaffolds that bind isotoxins. This molecular understanding will permit an ability to design binding clefts to recognize new peptide motifs present in threat agents.

* Including viruses and prions.

Critical to these efforts are:

1) high-throughput measurements of the affinities and kinetics of binding between the protein scaffold and known binding sequences,
2) the development and testing of computational models that predict naturally occurring binding sequences, and
3) an ability to deploy computational models to engineer new binding clefts to create bifunctional affinity reagents against families of threat agents.

It is expected that the development of a means to rapidly identify high efficacy mechanisms of bio-molecular interactions between protein scaffolds with both natural and modified targets will provide the needed ability to rapidly create new affinity reagents that can be deployed with existing detection strategies to neutralize evolving threats.

For the Department of Homeland Security, the objectives of the research are to investigate nucleic acid and immunoassay detection methods for biological threat agents and to be able to discriminate from non-pathogenic near neighbors. DNAs and BSL-1/BSL-2 whole organisms are used in this research. For HHS and EPA projects, our research investigates methods for detection and determination of food and waterborne pathogens.

For the Laboratory Directed Research and Development (LDRD) effort, the objective was to investigate stable platforms for novel molecular recognition elements for pathogen detection. Our role is to develop tools for organic signatures characterization in biological materials for forensic attribution. This generically includes both volatile and non-volatile organic components as either direct or indirect signatures of the culture media, preparation conditions, or treatment processes. We are using mass spectrometry methods to elucidate functional changes in the proteomes of infectious bacteria under relevant growth conditions, host-derived cell-lines during infection, or with overexpressed pathogen secreted proteins.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category A and B Priority Pathogens
- **Overlap Select Agents**
  Including NIAID Category A Priority Pathogens
- **Other pathogens or toxins**
  Including non-Select Agent, NIAID Category B Priority Pathogens

All Select Agent Toxin(s) below the *de minimus* level and thus exempt from registration with the Select Agent Program.

III. Outdoor Studies:
None

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Sandia National Laboratories

2. Where is it located (provide both address and geographical location)?

P. O. Box 5800
Albuquerque, New Mexico 87185

3. Floor area of laboratory areas by containment level.

BL1 (sqM)	1273
BL2 (sqM)	944
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	2217

4. The organizational structure of each facility.

I Total Number of Personnel 78

II Division of Personnel:

Military	0
Civilian	78

III Division of Personnel by Category:

Scientists	40
Engineers	7
Technicians	29
Administrative/Support	2

IV List the scientific disciplines represented in the scientific/engineering support staff.

Analytical Biochemistry
Analytical Chemistry
Analytical Mass Spectrometry
Bacteriology
Biochemistry

Bioengineering
Biofuel Production
Bioinformatics
Biology
Biology Engineering
Biomedical Engineering
Biophysics
Biotechnology
Cell Biology
Chemical Engineering
Chemistry
Computational Biologist
Electrical Engineering
Engineering
Environmental Engineering
Environmental Science
Genetics
Genomics
Geosciences
Immunology
Infectious Disease
Laser Electro-optics
Mass Spectrometry
Mass Spectrometry Biochemistry
Materials Science
Microbiology
Microfluidics
Molecular Biology
Molecular Spectroscopy and Imaging
Molecular Toxicology
Nanotechnology
Optical Spectroscopy
Pathogenesis
Physics
Protein Chemistry
Protein Engineering
Proteomics
Structural Biology
Virology

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 19

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Defense (DOD)
U.S. Department of Energy (DOE)
U.S. Department of Health and Human Services (HHS)
U.S. Department of Homeland Security (DHS)
Internal (Laboratory Directed Research and Development LDRD)
Other Governmental Agencies

VII What are the funding levels for the following program areas:

Research	$46,533,000
Development	$ 0
Test and evaluation	$ 324,000
Total	$46,857,000

VIII Briefly describe the publication policy of the facility:

Scientists are encouraged to publish their results in the peer-reviewed scientific literature as well as present their work at national and international professional meetings.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Liu, H., and Bachand, G.D. (2010). Understanding energy dissipation and thermodynamics in biomotor-driven nanocomposite assemblies. Soft Matt. (DOI: 10.1039/C0SM01106A).

Aaron, J.S., Greene, A.C., Kotula, P.G., Bachand, G.D., and Timlin, J.A. (2010).Advanced optical imaging reveals the dependence of particle geometry on interactions between CdSe quantum dots and immune cells. Small (DOI: 10.1002/smll.201001619).

Carroll-Portillo, A., and Bachand, G.D. (2009). Directed attachment of antibodies to kinesin-powered molecular shuttles. Biotechnol. Bioeng. 104(6): 1182-1188.

Carroll-Portillo, A., Bachand, M., Greene, A.C, and Bachand, G.D. (2009). Capture and transport of protein analytes with kinesin-based nanoharvesters. Small 5(16): 1835-1840.

Bachand, G.D., Hess, H., Ratna, B., Satir, P., and Vogel, V. (2009). "Smart Dust" biosensors powered by biomolecular motors. Lab Chip 9(12): 1661 - 1666 (Invited review).

Tucker, R. Saha, A., Katira, P., Bachand, M., Bachand, G.D., and Hess, H. (2009). Temperature-compensation for hybrid devices: Kinesin's Km is temperature-independent. Small 5(11): 1279-1282.

Rios, L. and Bachand, G.D. (2009). Multiplex transport and detection of cytokines using kinesin-driven molecular shuttles. Lab Chip 9: 1005-1010.

K.E. Achyuthan, P.D. Adams, B.A. Simmons & A.K. Singh, "Spectroscopic Analyses of the Biofuels-critical Phytochemical, Coniferyl Alcohol and its Laccase-catalyzed Oxidation products." Molecules, 14: 4758-4778, 2009.

J. C. Harper, S. M. Brozik, J. H. Flemming, J. L. McClain, R. Polsky, D. Raj, G. A. Ten Eyck, D. R. Wheeler & K. E. Achyuthan, "Fabrication and Testing of a Microneedles Sensor Array for Biofuel Applications." ACS Appl. Mater. Interfaces, 1: 1591-1598, 2009.

Z. Zhou, Y. Tang, D. G. Whitten & K. E. Achyuthan, "A new High-throughput Screening Protease Assay based upon Supramolecular Self-Assembly." ACS Appl. Mater. Interfaces, 1: 162-170, 2009.

K.E. Achyuthan, J.L. McClain, Z. Zhou, D.G. Whitten & D.W. Branch. "Spectroscopic Analyses of the Noncovalent Self-Assembly of Cyanines Upon Various Nucleic Acid Scaffolds." Analyt. Sci., 25: 469-474, 2009.

K.E. Achyuthan, J.L. McClain & D. Raj. "Orthogonal, Spectroscopic High-throughput Screening of Laccase-Catalyzed p-Cresol Oxidation." Comb. Chem. HTS., 12: 678-689, 2009.

K.E. Achyuthan, D.C. Arango, E.L. Carles, C.E. Cutler, L.A. Meyer & S.M. Brozik. "Luminescent Investigations of Terbium (III) Biosorption as a Surrogate for Heavy Metals and Radionuclides." Mol. Cell. Biochem., 327: 87-92, 2009.

H. K. Baca, E.C. Carnes, C.E. Ashley, D.M. Lopez, C. Douthit, S.Karlin, and C.J. Brinker, Cell-directed-assembly: Directing the formation of nano/bio interfaces and architectures with living cells, Biochimica et Biophysica Acta (BBA) - General Subjects, Accepted Nov 2010.

J.C. Harper, C. Khirpin, E.C. Carnes, C.E. Ashley, D.M. Lopez, T. Savage, H. Jones, R. Davis, D. Nunez, L.M. Brinker, B.J. Kaehr, S. Brozik, and C.J. Brinker. Cell-Directed Integration into 3D Lipid-Silica Nanostructured Matrices, ACS Nano 2010 4 (10), 5539-5550.

Z. Chen, Y.B. Jiang, D.R. Dunphy, D.P. Adams, C. Hodges, N.G. Liu, N. Zhang, G. Xomeritakis, N.R. Aluru, S.J. Gaik, H.W. Hillhouse, and C.J. Brinker, DNA translocation through an array of kinked nanopores, Nature Materials 9 (8) 667-675 (Aug 2010)

B.J. Kaehr, and C. Jeffrey Brinker, Using bacterial cell growth to template catalytic asymmetry, Chemical Communications 46(29) 5268:5270 (2010)

Constantine Y. Khripin, C. Jeffrey Brinker, and Bryan Kaehr, Mechanically tunable

multiphoton fabricated protein hydrogels investigated using atomic force microscopy, Soft Matter, 6(10), 2842-2848 (2010).

E.L. Kendall, E. Mills, J.W. Liu, X.M. Jiang, C.J. Brinker, B.J. Kaehr, Salt-induced lipid transfer between colloidal supported lipid bilayers, Soft Matter 6(12) 2628-2632 (2010)

T. L. Ward, Y. S. Cheng, J. W. Liu, and C. J. Brinker, Aerosol fabrication of hollow mesoporous silica nanoparticles and encapsulation of L-methionine as a candidate drug cargo, Chemical Communications 46 (17), 3019-3021 (2010).

E.C. Carnes, D.M. Lopez, N.P. Donegan, A. Cheung, H. Gresham, G.S. Timmins, C.J. Brinker, Confinement-induced quorum sensing of individual Staphylococcus aureus bacteria, Nature Chemical Biology 6 (2010) 41-45 (2010)

Spendier, K., A. Carroll-Portillo, et al. (2010). "Distribution and dynamics of RBL IgE receptors (FcÎµRI) observed on planar ligand-presenting surfaces." Biophysical Journal 99: 388-397.

Davis, R. W., J. A. Timlin, et al. (2010). "Accurate detection of low levels of fluorescence emission in autofluorescent background: Francisella infected macrophage cells." Microscopy & Microanalysis 16(4): 478-487.

Carroll-Portillo, A., K. Spendier, et al. (2010). "Formation of a Mast Cell Synapse: Fc epsilon RI Membrane Dynamics upon Binding Mobile or Immobilized Ligands on Surfaces." Journal of Immunology 184(3): 1328-1338.

Aaron, J. S., A. Greene, et al. (2011). "Advanced Optical Imaging Reveals Dependence of Particle Geometry on Interactions between CdSe Quantum Dots and Immune Cells." Small: in press.

James CD, Moorman MW, Carson BD, Branda CS, Lantz JW, Manginell RP, Martino A, Singh AK. Nuclear translocation kinetics of NF-kappaB in macrophages challenged with pathogens in a microfluidic platform. Biomed Microdevices. 2009 Jun; 11(3):693-700. PubMed PMID: 19169824.

"Neutron reflectometry study of the conformation of HIV Nef bound to lipid membranes" Biophysical Journal 2010, 99, 1940-1948

Stewart T.A., Trudell D., Alam T., Ohlin C.A., Lawler C., Casey W., Jett S, and Nyman M. (2009) Enhanced Water Purification: A Single Atom Makes a Difference. Environmental Science and Technology, 43(14), 5416-5422

Altman, S. J.; L. K. McGrath, H. D. T. Jones, A. L Sanchez, R. Noek, P. Clem, A. Cook, C. K. Ho, Systematic analysis of micromixers to minimize biofouling on reverse osmosis membranes, Water Research, 44(12), 3545- 3554, 2010.

Van Wagner, E. M., B. D. Freeman, M. M. Sharma, M. A. Hickner, and S. J. Altman, Polyamide Desalination Membrane Characterization and Surface Modification to Enhance Fouling Resistance, SAND2010-5540, Sandia National Laboratories, Albuquerque, NM, 2010.

Altman, S. J., M. Cappelle, A. Sattler, R. Everett, W. Holub, H. Anderson, T. Mayer, and F. McDonald, Nanofiltration Treatment Options for Thermoelectric Power Plant Water Treatment Demands, SAND2010-3915, Sandia National Laboratories, Albuquerque, NM, 2010.

Achyuthan, Komandoor Elayavalli; Achyuthan, Ann Mary; Adams, Paul David; Dirk, Shawn Matthew; Harper, Jason Carl; Simmons, Blake Alexander; Singh, Anup Kumar. "Supramolecular self-assembled chaos: polyphenolic lignin's barrier to cost-effective lignocellulosic biofuels," Molecules (2010), 15, 8641-8688.

Yang, Y., Dec, J., Dronniou, N., Simmons, B.A. "Characteristics of Isopentanol as a Fuel for HCCI engines," Society of Automobile Engineers, September 2010

Chandrasekaran, Aarthi; Bharadwaj, Rajiv; Park, Joshua I.; Sapra, Rajat; Adams, Paul D.; Singh, Anup K. A "Microscale Platform for Integrated Cell-Free Expression and Activity Screening of Cellulases," Journal of Proteome Research, 9(11), 5677-5683, 2010.

Bharadwaj, R., A. Wong, B. Knierim, S. Singh, B.M. Holmes, M. Auer, B.A. Simmons, P.D. Adams, A.K. Singh, "High-Throughput Enzymatic Hydrolysis of Lignocellulosic Biomass via In-Situ Regeneration," Bioresource Technology, 102, 1329-1337, 2011.

Bharadwaj, R., Z. Chen, S. Datta, B.M. Holmes, R. Sapra, B.A. Simmons, P.D. Adams, A.K. Singh, "Microfluidic Glycosyl Hydrolase Screening for Biomass-to-Biofuels Conversion," Analytical Chemistry, 82, 9135-9592, 2010. (Featured cover article)

Pereira, Jose H.; Chen, Zhiwei; McAndrew, Ryan P.; Sapra, Rajat; Chhabra, Swapnil R.; Sale, Kenneth L.; Simmons, Blake A.; Adams, Paul D. "Biochemical characterization and crystal structure of endoglucanase Cel5A from the hyperthermophilic Thermotoga maritima," Journal of Structural Biology (2010), 172(3), 372-379.

Davis, R. W.; Timlin, J. A.; Kaiser, J. N.; Sinclair, M. B.; Jones, H. D. T.; Lane, T. W., "Accurate Detection of Low Levels of Fluorescence Emission in Autofluorescent Background: Francisella-Infected Macrophage Cells," Microscopy and Microanalysis 2010, 16, (04), 478-487.

Ryan W. Davis, Jerilyn A. Timlin, Rachel Noek, Julia N. Kaiser, Howland D. T. Jones, and Todd W. Lane, "Accurate detection of low levels of fluorescence emission in autofluorescent background: Francisella infected macrophage cells," Microscopy & Microanalysis 16 (4), 478-487 (2010).

O. P. Cetinkol, D. C. Dibble, G. Cheng, M. S. Kent, B. Knierim, M. Auer, D. E. Wemmer, J. G. Pelton, Y. B. Melnichenko, J. Ralph, B. A. SImmons, B. M. Holmes "Understanding the impact of ionic liquid pretreatment on eucalyptus," Biofuels (2010), 1(1), 33-46.

Patel, K.D. and Perroud, T.D, "The Microflow cytometer" Book chapter 14: "Optical MicroFACS" ED. Ligler and Kim, 2010

Hukari, K. W., K. D. Patel, et al. (2010). "An ultra-high temperature flow-through capillary device for bacterial spore lysis." Electrophoresis 31(16): 2804-2812.

A.H. Hecht, G.J. Sommer, R.H. Durland, X. Yang, A.K. Singh, A.V. Hatch. "Aptamers as Affinity Reagents in an Integrated Electrophoretic Lab-on-a-Chip Platform" Analytical Chemistry, 82, 8813-8820 (2010).

Van Benthem, M.H., Lane, T.W., Davis, R.W., Lane P. D., and Keenan M.R., 2010. "PARAFAC Modeling of Three-Way Hyperspectral Images: Endogenous Fluorophores as Health Biomarkers in Aquatic Species," Chemomet. Intel. Lab. Sys. Accepted for publication

Stachowiak, J. C.; Hayden, C. C.; Sanchez, M. A. A.; Wang, J.; Bunker, B. C.; Voigt, J. A.; Sasaki, D. Y. Langmuir "Targeting Proteins to Liquid-Ordered Domains in Lipid Membranes" (web publication date: Dec. 14, 2010).

Kent, Michael S.; Murton, Jaclyn K.; Sasaki, Darryl Y.; Satija, Sushil; Akgun, Bulent; Nanda, Hirsh; Curtis, Joseph E.; Majewski, Jaroslaw; Morgan, Christopher R.; Engen, John R. "Neutron Reflectometry Study of the Conformation of HIV Nef Bound to Lipid Membranes" Biophys. J. 2010, 99, 1940 - 1948.

Siu, Howard; Duhamel, Jean; Sasaki, Darryl Y.; Pincus, Jennifer L. Langmuir "Nanodomain Formation in Lipid Membranes Probed by Time-Resolved Fluorescence" 2010, 26(13), 10985 - 10994.

Stachowiak, Jeanne C.; Hayden, Carl C.; Sasaki, Darryl Y., "Steric Confinement of Proteins on Lipid Membranes Can Drive Curvature and Tubulation" Proceedings of the National Academy of Sciences of the United States of America, 2010, 107(17), 7781 - 7786.

Kim, H., Bartsch, M.S., Renzi, R.F., Pezzola, G.L., Remillard, E.M., Kittlaus, E.A., He, J., and Patel, K.D. "Digital Microfludic Hub for Automated Nucleic Acid Sample Preparation," The 14th International Conference on Miniaturized Systems for Chemistry and Life Sciences (2010), 2035-2037, Groningen, Netherlands.

Daniel Klein-Marcuschamer, Piotr Oleskowicz-Popiel, Blake A. Simmons, and Harvey W. Blanch. "Technoeconomic analysis of biofuels: a wiki-based platform for lignocellulosic biorefineries," Biofuels and Bioenergy, (2010) 34(12), 1914-1921, 2010

Hanbin Liu, Jose Henrique Pereira, Paul D. Adams, Rajat Sapra, and Blake A. Simmons, Kenneth L. Sale. "Molecular Simulations Provide New Insight into Role of Accessory Immunoglobulin-like Domain of Cel9A," FEBS Letters (2010) 584(15), 3431-3435.

Brennan T.C., Blanch H.W., Simmons B.A., and Holmes B.M. "Recovery of Sugars from Ionic Liquid Biomass Liquor by Solvent Extraction," Bioenerg. Res. (2010) 3:123-133.

Han J., Singh S., Sun L., Simmons B.A., Auer M. and Parvin B. "Chemical Profiling of the Plant Cell Wall through Raman Microspectroscopy," Proceedings of IEEE International Symposium on Biomedical Imaging, 2010.

Arora R., Manisseri C., Li C., Scheller H.V., Simmons B.A., Singh S. "Monitoring and Analyzing Process Streams towards Understanding Ionic Liquid Pretreatment of Switchgrass (Panicum virgatum)," BioEnergy Research (2010) 3:134-145.

Simmons B.A., Loque D., Ralph J. "Advances in modifying lignin for enhanced biofuel production," Current Opinion in Plant Biology, 2010, 13(3), 312-319.

DeAngelis K.M., Gladden J.M., Allgaier M., D'haeseleer P., Fortney J.L., Reddy A., Hugenholtz P., Singer S.W., Vander Gheynst J., Silver W.L., Simmons B.A., and Hazen T.C. "Strategies for Enhancing the Effectiveness of Metagenomic-based Enzyme Discovery in Lignocellulolytic Microbial Communities," BioEnergy Research. In Press 2010.

Simmons B.A., Singh S., Holmes B.M., Blanch H.W. "Ionic Liquid Pretreatment," Chemical Engineering Progress, 106(3), 50-55, 2010.

Achyuthan K.E., Adams P.D., Simmons B.A., Singh A.K. - "Spectroscopic Analyses of the Biofuels-Critical Phytochemical Coniferyl Alcohol and Its Enzyme-Catalyzed Oxidation Products,"Molecules, 14(11), 4758-4778, 2010.

Achyuthan K.E., Adams P.D., Datta S., Simmons B.A., Singh A.K. " Hitherto unrecognized fluorescence properties of coniferyl alcohol," Molecules, 15 1645-1667, 2010.

Liu H., Sale K.L., Holmes B.M., Simmons B.A., Singh S. "Understanding the Interactions of Cellulose with Ionic Liquids: A Molecular Dynamics Study," Journal of Physical Chemistry B, 114(12), 4293-4301, 2010.

Li C, Knierim B, Manisseri C, Scheller HV, Vogel K, Simmons B, Singh S. "Comparison of dilute acid and ionic liquid pretreatment of switchgrass: Biomass recalcitrance, delignification and enzymatic saccharification," Bioresource Technology, 101 (13) 4900-4906 July 2010.

Datta S., Holmes B., Park J.I., Chen Z., Dibble D.C., Hadi M.Z., Blanch H.W., Simmons B.A., and Sapra R. "Ionic liquid tolerant hyperthermophilic cellulases for biomass

pretreatment and hydrolysis," Green Chemistry, 12(2), 338-345, 2010.

Wurtzel O, Sapra R, Chen F, Zhu Y, Simmons BA, Sorek R. "A single-base resolution map of an archaeal transcriptome," Genome Research, 20(1), 133-141, 2010.

Allgaier, Martin; Reddy, Amitha; Park, Joshua I.; Ivanova, Natalia; D'Haeseleer, Patrik; Lowry, Steve; Sapra, Rajat; Hazen, Terry C.; Simmons, Blake A.; Vander Gheynst, Jean S.; Hugenholtz, Philip. "Targeted discovery of glycoside hydrolases from a switchgrass-adapted compost community," PLoS One, 5(1), e8812, 2010.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
The Sandia National Laboratory (SNL) Chem/Bio Defense Program is an applied research program designed to develop and demonstrate technologies and systems that can be used to mitigate the impact of attacks on civilian populations with chemical or biological agents. Specific aims include:

1. Analyze pathogenic mechanisms caused by toxins interacting with cell membranes;
2. Development of diagnostic and detection technologies for toxins, bacteria, and viruses by applying micro-separations technology;
3. Development of technologies for the characterization of aerosolized particles using optics, among many others. Work with biological agents at Sandia also includes work in nanotechnology and biofuels.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category B Priority Pathogens
- **USDA Select Agents and Toxins**
- **Other pathogens or toxins**
  Including non-Select Agent, NIAID Category A, B and C Priority Pathogens

All Select Agent Toxin(s) below the *de minimus* level and thus exempt from registration with the Select Agent Program.

III. Outdoor Studies:
None

[*] Including viruses and prions.

Form A, Part 2 (iii)

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

CDC Mass Spectrometry Toxin Laboratory

2. Where is it located (provide both address and geographical location)?

Centers for Disease Control and Prevention (CDC)
U.S. Department of Health and Human Services
4770 Buford Highway
Mail stop F-47
Atlanta, Georgia 30341

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	114
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	114

4. The organizational structure of each facility.

I Total Number of Personnel 30

II Division of Personnel:

Military	0
Civilian	30

III Division of Personnel by Category:

Scientists	27
Engineers	0
Technicians	0
Administrative/Support	3

IV List the scientific disciplines represented in the scientific/engineering support staff.

Analytical Biochemistry
Analytical Chemistry
Analytical Mass Spectrometry
Biochemistry

Mass Spectrometry
Microbiology

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 4

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Health and Human Services (HHS)

VII What are the funding levels for the following program areas:

Research	$1,900,000
Development	$ 0
Test and evaluation	$ 0
Total	$1,900,000

VIII Briefly describe the publication policy of the facility:

Scientists are encouraged to publish their results in the peer reviewed scientific literature as well as present their work at national and international professional meetings.

The clearance policy for information products disseminated outside CDC for public use is available online at: http://www.cdc.gov/od/science/policies/clearance.htm

CDC Policy on "Oversight and clearance of dual use research of concern," is available online at: http://www.cdc.gov/OD/foia/policies/policy516.pdf

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Barr JR, Boyer AE, Quinn CP. Anthrax: modern exposure science combats a deadly, ancient disease. J Expo Sci Environ Epidemiol. 2010 Nov;20(7):573-4.

Crawford MA, Burdick MD, Glomski IJ, Boyer AE, Barr JR, Mehrad B, Strieter RM, Hughes MA. Interferon-inducible CXC chemokines directly contribute to host defense against inhalational anthrax in a murine model of infection. PLoS Pathog. 2010 Nov 18; 6(11):e1001199.

Kalb SR, Baudys J, Egan C, Smith TJ, Smith LA, Pirkle JL, Barr JR. Clostridium baratii type F neurotoxin cleaves synaptobrevin-2 with different substrate recognition requirements

than clostridium botulinum type F neurotoxin. Appl Environ Microbiol. 2010 Dec 17. [Epub ahead of print].

Kalb SR, Garcia-Rodriguez C, Lou J, Baudys J, Smith TJ, Marks JD, Smith LA, Pirkle JL, Barr JR. Extraction of BoNT/A, /B, /E, and /F with a single, high affinity monoclonal antibody for detection of botulinum neurotoxin by Endopep-MS. PLoS One. 2010 Aug 17; 5(8):e12237.

Williamson YM, Moura H, Schieltz D, Rees J, Woolfitt AR, Pirkle JL, Sampson JS, Tondella ML, Ades E, Carlone G, Barr JR. Mass spectrometric analysis of multiple pertussis toxins and toxoids. J Biomed Biotechnol. 2010; 2010:942365.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
The CDC Mass Spectrometry Toxin Laboratory has successfully developed toxin assays that are critical for better detection and diagnosis during a public health response to biological toxins. The laboratory uses advanced mass spectrometry techniques to measure peptides and proteins that are in the pathogenic pathway of the infectious agent or toxin and uses these measurements to identify and track infection or poisoning.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category B Priority Pathogens
- **Overlap Select Agents**
  Including NIAID Category A Priority Pathogens
- **Other pathogens or toxins**
  Including non-Select Agent, NIAID Category A and B Priority Pathogens

Some Select Agent Toxin(s) below the *de minimus* level and thus exempt from registration with the Select Agent Program.

III. Outdoor Studies:
None

[*] Including viruses and prions.

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

CDC, NCEZID, Division of Vector Borne Diseases (DVBD)

2. Where is it located (provide both address and geographical location)?

Centers for Disease Control and Prevention (CDC)
U.S. Department of Health and Human Services
3150 Rampart Road
Fort Collins, Colorado 80521

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	66
BL3 (sqM)	1142
BL4 (sqM)	0
Total (sqM)	1208

4. The organizational structure of each facility.

I Total Number of Personnel 160

II Division of Personnel:

Military	0
Civilian	160

III Division of Personnel by Category:

Scientists	86
Engineers	6
Technicians	0
Administrative/Support	68

IV List the scientific disciplines represented in the scientific/engineering support staff.

Biology
Ecology
Electrical Engineering
Entomology

Epidemiology
Industrial Hygiene Engineering
Medicine
Microbiology
Molecular Biology
Physicians
Virology

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 55

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Health and Human Services (HHS)

VII What are the funding levels for the following program areas:

Research	$ 921,552
Development	$ 460,756
Test and evaluation	$ 460,756
Total	$1,843,064

VIII Briefly describe the publication policy of the facility:

Publication is encouraged and managed by editorial and clearance policies conducted at all levels of the Agency.

The clearance policy for information products disseminated outside CDC for public use, is available online at: http://www.cdc.gov/od/science/policies/clearance.htm

CDC Policy on "Oversight and clearance of dual use research of concern," is available online at: http://www.cdc.gov/OD/foia/policies/policy516.pdf

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Biggins DE, Godbey JL, Gage KL, Carter LG, Montenieri JA. Vector Control Improves Survival of Three Species of Prairie Dogs (Cynomys) in Areas Considered Enzootic for Plague. Vector Borne Zoonotic Dis. 2010 January/February; 10(1): 17-26.

Brown HE, Ettestad P, Reynolds PJ, Brown TL, Hatton ES, Holmes JL, Glass GE, Gage KL,

Eisen RJ. Climatic predictors of the intra- and inter-annual distributions of plague cases in New Mexico based on 29 years of animal-based surveillance data. Am. J. Trop. Med. Hyg. 2010 Jan; 82(1):95-102.

Brinkerhoff RJ, Collinge SK, Ray C, Gage KL. Rodent and Flea Abundance Fail to Predict a Plague Epizootic in Black-Tailed Prairie Dogs. Vector Borne Zoonotic Dis. 2010 January/February; 10(1): 47-52.

Bearden SW, Brubaker RR. Recent Findings Regarding Maintenance of Enzootic Variants of Yersinia pestis in Sylvatic Reservoirs and Their Significance in the Evolution of Epidemic Plague. Vector-Borne and Zoonotic Diseases Volume 10, Number 1, 2010.

Nakazawa Y, Williams RAJ, Peterson AT, Mead PS, Kugeler KJ, Petersen J M. Ecological Niche Modeling of Francisella tularensis Subspecies and Clades in the United States. Am. J. Trop. Med. Hyg., 82(5), 2010, pp. 912-918.

Eisen RJ, Griffith KS, Borchert JN, MacMillan K, Apangu T, Owor N, Acayo S, Acidri R, Zielinski-Gutierrez E, Winters AM, Enscore RE, Schriefer ME, Beard CB, Gage KL, Mead PS. Assessing Human Risk of Exposure to Plague Bacteria in Northwestern Uganda Based on Remotely Sensed Predictors. Am. J. Trop. Med. Hyg., 82(5), 2010, pp. 904-911.

Nguku PM, Sharif SK, Mutonga D, Amwayi S, Omolo J, Mohammed O, Farnon EC, Gould LH, Lederman E, Rao C, Sang R, Schnabel D, Feikin DR, Hightower A, Njenga MK, Breiman RF. An Investigation of a Major Outbreak of Rift Valley Fever in Kenya: 2006-2007. Am J Trop Med Hyg. 2010 Aug; 83(2 Suppl):5-13.

Anyangu AS, Gould LH, Sharif SK, Nguku PM, Omolo JO, Mutonga D, Rao CY, Lederman ER, Schnabel D, Paweska JT, Katz M, Hightower A, Njenga MK, Feikin DR, Breiman RF. Risk Factors for Severe Rift Valley Fever Infection in Kenya, 2007. Am J Trop Med Hyg. 2010 Aug; 83(2 Suppl):14-21.

Mohamed M, Mosha F, Mghamba J, Zaki SR, Shieh WJ, Paweska J, Omulo S, Gikundi S, Mmbuji P, Bloland P, Zeidner N, Kalinga R, Breiman RF, Njenga MK. Epidemiologic and clinical aspects of a Rift Valley fever outbreak in humans in Tanzania, 2007. Am J Trop Med Hyg. 2010 Aug; 83(2 Suppl):22-27.

Sang R, Kioko E, Lutomiah J, Warigia M, Ochieng C, O'Guinn M, Lee JS, Koka H, Godsey M, Hoel D, Hanafi H, Miller B, Schnabel D, Breiman RF, Richardson J. Rift Valley fever virus epidemic in Kenya, 2006/2007: the entomologic investigations. Am J Trop Med Hyg. 2010 Aug; 83(2 Suppl):28-37.

Shieh WJ, Paddock CD, Lederman E, Rao CY, Gould LH, Mohamed M, Mosha F, Mghamba J, Bloland P, Njenga MK, Mutonga D, Samuel AA, Guarner J, Breiman RF, Zaki SR. Pathologic studies on suspect animal and human cases of Rift Valley fever from an

outbreak in Eastern Africa, 2006-2007. Am J Trop Med Hyg. 2010 Aug; 83(2 Suppl):38-42.

Ari TB, Gershunov A, Tristan R, Cazelles B, Gage K, Stenseth NC. Interannual Variability of Human Plague Occurrence in the Western United States Explained by Tropical and North Pacific Ocean Climate Variability. Am J Trop Med Hyg. 2010 Sep; 83(3):624-32.

Reese SM, Dietrich G, Dolan MC, Sheldon SW, Piesman J, Petersen JM, Eisen RJ. Transmission dynamics of Francisella tularensis subspecies and clades by nymphal Dermacentor variabilis (Acari: Ixodidae). Am J Trop Med Hyg. 2010 Sep; 83(3):645-52.

Borchert JN, Enscore RE, Eisen RJ, Atiku LA, Owor N, Acayo S, Babi N, Montenieri JA, Gage KL. Evaluation of Rodent Bait Containing Imidacloprid for the Control of Fleas on Commensal Rodents in a Plague-Endemic Region of Northwest Uganda. J. Med. Entomol. 47(5): 842-850 (2010); DOI: 10.1603/ME09221.

Friggens MM, Parmenter RR, Boyden M, Ford PL, Gage K, Keim P. Flea abundance, diversity, and plague in Gunnison's prairie dogs (Cynomys gunnisoni) and their burrows in montane grasslands in northern New Mexico. J Wildl Dis. 2010 Apr;46(2):356-367.

Sean P. Maher ,* Christine Ellis , Kenneth L. Gage , Russell E. Enscore , and A. Townsend Peterson. Range-wide Determinants of Plague Distribution in North America. Am. J. Trop. Med. Hyg., 83(4), 2010, pp. 736-742.

Yin Z, Wang H, Yang J, Luo H, Li Y, Hadler SC, Sandhu HS, Fischer M, Jiang Y, Zhang Z, Liu G, Li L, Johnson BW, Liang X, and the Acute Meningitis and Encephalitis Syndrome (AMES) Study Group. Japanese Encephalitis Disease Burden and Clinical Features of Japanese Encephalitis in Four Cities in the People's Republic of China. Am. J. Trop. Med. Hyg., 83(4), 2010, pp. 766-773.

Yen NT, Duffy MR, Hong NM, Hien NT, Fischer M, Hills SL. Surveillance for Japanese Encephalitis in Vietnam, 1998-2007. Am. J. Trop. Med. Hyg., 83(4), 2010, pp. 816-819.

Robinson JS, Featherstone D, Vasanthapuram R, Biggerstaff BJ, Desai A, Ramamurty N, Chowdhury AH, Sandhu HS, Cavallaro KF, Johnson BW. Evaluation of three commercially available Japanese encephalitis virus IgM enzyme-linked immunosorbent assays. Am J Trop Med Hyg. 2010 Nov; 83(5):1146-55.

Morelli G, Song Y, Mazzoni CJ, Eppinger M, Roumagnac P, Wagner DM, Feldkamp M, Kusecek B, Vogler AJ, Li Y, Cui Y, Thomson NR, Jombart T, Leblois Rl, Lichtner P, Rahalison L, Balloux F, Keim P, Wirth T, Ravel J, Yang R, Carniel E, Achtman M. Yersinia pestis genome sequencing identifies patterns of global phylogenetic diversity. Nature Genetics. 2010 Dec; 42(12):1140-3.

Johansson A. Genotyping of Francisella tularensis, the causative agent of tularemia. 2010.

Journal of AOAC International. 93 (6).

Walker RE, Petersen JM, Stephens KW, Dauphin LA. Optimal swab processing recovery method for detection of bioterrorism-related Francisella tularensis by real-time PCR. J Microbiol Methods. 2010 Oct; 83(1):42-7.

Delorey MJ, Yockey BM, Young JW, Sheldon SW, Reese SM, Schriefer ME, Petersen JM. Virulence differences among Francisella tularensis subsp. tularensis clades in mice. PLoS One. 2010 Apr 16; 5(4):e10205.

Molins CR. Subpopulations of Francisella tularensis ssp. tularensis and holarctica: identification and associated epidemiology. Future Microbiol. 2010 Apr;5(4):649-61.

Johansson A, Celli J, Conlan W, Elkins KL, Forsman M, Keim PS, Larsson P, Manoil C, Nano FE, Sjöstedt A. Objections to the transfer of Francisella novicida to the subspecies rank of Francisella tularensis. Int J Syst Evol Microbiol. 2010 Aug; 60(Pt 8):1717-8.

Eds. RL Guerrant, DH Walker, PF Weller. Plague. Elsevier Churchill Livingstone, Philadelphia, in press.

Calanan RM, Rolfs RT, Summers J, Coombs J, Amdio J, Holbrook J. Tularemia outbreak associated with outdoor exposure along the western side of Utah Lake, Utah, 2007. Public Health Rep. 2010 Nov-Dec; 125(6):870-6.

McKelroy KM, Blagburn BL, Breitschwerdt EB, McQuiston JH. Bd. Flea-associated zoonotic diseases of cats in the USA: bartonellosis, flea-borne rickettsioses, and plague. Trends in Parasitology; 2010; 26: 197-204.

Eisen RJ, Schotthoefer AM, Montenieri JA, Homles JL, Bobrov AG, Bearden SW, Perry RD, Gage KL. Biofilm formation is not required for early-phase transmission of Yersinia pestis. Microbiology 156:2216-2225, 2010.

Desrosiers DC, Mier I Jr, Abney J, Paulley JT, Fetherston JD, Salazar JC, Radolf JD, Perry RD. Znu is the predominant zinc importer in Yersinia pestis during in vitro growth but is not essential for virulence. Infect Immun. 2010 Dec; 78(12):5163-77. PubMed PMID: 20855510.

Lindsey NP, Staples JE, Hills SL. Japanese encephalitis vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP). MMWR 2010 (Mar); 59(No. RR-1):1-27.

Griggs AC, Fischer M. Japanese encephalitis among travelers from non-endemic countries, 1973-2008. Am J Trop Med Hyg 2010 (May); 82(5):930-936.

Hossain MJ, Gurley ES, Montgomery S, Petersen L, Sejvar J, Fischer M, Panella A, Powers

AM, Nahar N, Uddin AK, Rahman ME, Ekram AR, Luby SP, Breiman RF. Hospital-based surveillance for Japanese encephalitis at four sites in Bangladesh, 2003-2005. Am J Trop Med Hyg 2010 (Feb); 82(2):344-349.

Frederickson S, Maruyama T, Bowdish KS, Roehrig JT, Blair CD. A human epitope map for the glycoproteins of Venezuelan equine encephalomyelitis virus reveals a new E2 epitope associated with significant neutralizing activity. PLOS Neglected Pathogens 2010, 4:739.

Phillips AT, Mossel EC, Ledermann JP, Welte T, Dow SW, Olson KE, Powers AM. Cationic Liposome-DNA Complexes (CLDC) Protect Outbred Mice from Lethal Western Equine Encephalitis Virus (WEEV) Challenge. Antiviral Research. 2010, Aug; 87(2):195-203.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
The Division of Vector-Borne Diseases (DVBD) strives to protect the nation from bacterial and viral diseases transmitted by mosquitoes, ticks and fleas. DVBD's biodefense work focuses on development and implementation of epidemiology and surveillance; prevention, control and decontamination; vaccine development and improved diagnostics for diagnosis, detection and characterization of several vector-borne pathogens including various bacteria and alphaviruses. Additionally, DVBD serves as the national reference laboratory for these pathogens.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category A and B Priority Pathogens
- **Overlap Select Agents**
  Including NIAID Category A and B Priority Pathogens
- **USDA Select Agents and Toxins**
  Including NIAID Category B Priority Pathogens
- **Other pathogens or toxins**
  Including non-Select Agent, NIAID Category B and C Priority Pathogens

III. Outdoor Studies:
None

[*] Including viruses and prions.

Form A, Part 2 (iii)

National biological defence research and development programme

III. Facilities

1. **What is the name of the facility?**

   CDC, Office of Infectious Diseases (OID)

2. **Where is it located (provide both address and geographical location)?**

   Centers for Disease Control and Prevention (CDC)
   U.S. Department of Health and Human Services
   1600 Clifton Road N.E.
   Atlanta, Georgia 30333

3. **Floor area of laboratory areas by containment level.**

BL2 (sqM)	281
BL3 (sqM)	2215
BL4 (sqM)	962
Total (sqM)	3458

4. **The organizational structure of each facility.**

   I Total Number of Personnel 696

   II Division of Personnel:

Military	0
Civilian	696

   III Division of Personnel by Category:

Scientists	232
Engineers	136
Technicians	42
Administrative/Support	286

   IV List the scientific disciplines represented in the scientific/engineering support staff.

   Biology
   Environmental Engineering
   Epidemiology
   Medicine

Microbiology
Molecular Biology
Public Health
Statistics

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 120

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Health and Human Services (HHS)
U.S. Environmental Protection Agency (EPA)
U.S. Department of Homeland Security (DHS)
Other Governmental Agencies

VII What are the funding levels for the following program areas:

Research	$81,672,476
Development	$ 6,213,348
Test and evaluation	$ 5,564,782
Total	$93,450,606

VIII Briefly describe the publication policy of the facility:

Publication is encouraged and managed by editorial and clearance policies conducted at all levels of the Agency.

The clearance policy for information products disseminated outside CDC for public use is available online at: http://www.cdc.gov/od/science/policies/clearance.htm

CDC Policy on "Oversight and clearance of dual use research of concern" is available online at: http://www.cdc.gov/OD/foia/policies/policy516.pdf

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Balish AL, Davis CT, Saad MD, El-Sayed N, Esmat H, Tjaden JA, Earhart KC, Ahmed LE, El-Halem MA, Hakem M A, Nassif SA, El-Ebiary EA, Taha M, Aly MM, Arafa A, O'Neill E, Xiyan X, Cox NJ, Donis RO, Klimov AI. Antigenic and genetic diversity of highly pathogenic avian influenza A (H5N1) viruses isolated in Egypt. Avian Diseases. 2010;

54:329-34.

Belisle SE, Tisoncik JR, Korth MJ, Carter VS, Proll SC, Swayne DE, Pantin-Jackwood M, Tumpey TM, Katze MG. Genomic profiling of tumor necrosis factor alpha (TNF-alpha) receptor and interleukin-1 receptor knockout mice reveals a link between TNF-alpha signaling and increased severity of 1918 pandemic influenza virus infection. Journal of Virology. 2010;84(24):12576-88.

Brown JN, Palermo RE, Baskin CR, Gritsenko M, Sabourin PJ, Long JP, Sabourin CL, Bielefeldt-Ohmann H, Garcia-Sastre A, Albrecht R, Tumpey TM, Jacobs JM, Smith RD, Katze MG. Macaque proteome response to highly pathogenic avian influenza and 1918 reassortant influenza virus infections. Journal of Virology. 2010; 84(22):12058-68.

Carlson CM, Turpin EA, Moser LA, O'Brien KB, Cline TD, Jones JC, Tumpey TM, Katz JM, Kelley LA, Gauldie J, Schultz-Cherry S. Transforming growth factor-Î²: Activation by neuraminidase and role in highly pathogenic H5N1 influenza pathogenesis. PLoS Pathogens. 2010;6(10):e1001136.

Cilloniz C, Pantin-Jackwood MJ, Ni C, Goodman AG, Peng X, Proll SC, Carter VS, Rosenzweig ER, Szretter KJ, Katz JM, Korth MJ, Swayne DE, Tumpey TM, Katze MG. Lethal dissemination of H5N1 influenza virus is associated with dysregulation of inflammation and lipoxin signaling in a mouse model of infection. Journal of Virology. 2010; 84(15):7613-24.

Davis CT, Balish AL, O'Neill E, Nguyen CV, Cox NJ, Xu X, Klimov A, Nguyen T, Donis RO. Detection and characterization of clade 7 high pathogenicity avian influenza H5N1 viruses in chickens seized at ports of entry and live poultry markets in Vietnam. Avian Diseases. 2010; 54:307-12.

Krause JC, Tumpey TM, Huffman CJ, McGraw PA, Pearce MB, Tsibane T, Hai R, Basler CF, Crowe JE Jr. Naturally occurring human monoclonal antibodies neutralize both 1918 and 2009 A(H1N1) pandemic influenza viruses. Journal of Virology. 2010; 84(6):3127-30.

Lednicky JA, Villanueva JM, Burke SA, Shively R, Shaw MW, Daniels DE, Hamilton SB, Donis RO. Validation of a method for preparing influenza H5N1 simulated samples. Journal of Virological Methods. 2010; 167:125-31.

Nguyen HH, Tumpey TM, Part H-J, Byun Y-H, Tran LD, Nguyen VD, Kilgore PE, Czerkinsky C, Katz JM, Seong BL, Song JM, Kim YB, Do HT, Nguyen T, Nguyen CV. Prophylactic and therapeutic efficacy of avian antibodies against influenza virus H5N1 and H1N1 in mice. PLoS ONE. 2010; 5(4):e10152.

Panday A, Singh N, Sambhara S, Mittal SK. Egg-independent vaccine strategies for highly pathogenic H5N1 influenza viruses. Human Vaccines. 2010; 6(2):1-11.

Perrone LA, Szretter KJ, Katz JM, Mizgerd JP, Tumpey TM. Mice lacking both TNF and IL-1 receptors exhibit reduced lung inflammation and delay in onset of death following infection with a highly virulent H5N1 virus. The Journal of Infectious Diseases. 2010; 202(8):1161-70.

Price GE, Soboleski MR, Lo C-Y, Misplon JA, Quirion MR, Houser KV, Pearce MB, Pappas C, Tumpey TM, Epstein SL. Single-dose mucosal immunization with a candidate universal influenza vaccine provides rapid protection from virulent H5N1, H3N2 and H1N1 viruses. PLoS ONE. 2010; 5(10):e13162.

Ranjan P, Jayashankar L, Deyde V, Zeng H, Davis WG, Pearce MB, Bowzard JB, Hoelscher MA, Jeisy-Scott V, Wiens ME, Gangappa S, Gubareva L, Garcia-Sastre A, Katz JM, Tumpey TM, Fujita T, Sambhara S. 5'PPP-RNA induced RIG-1 activation inhibits drug-resistant avian H5N1 as well as 1918 and 2009 pandemic influenza virus replication. Virology Journal. 2010; 7:102.

Rao SS, Kong W-P, Wei C-J, Hoeven NV, Gorres JP, Nason M, Andersen H, Tumpey TM, Nabel GJ. Comparative efficacy of hemagglutinin, nucleoprotein, and matrix 2 protein gene-based vaccination against H5N1 influenza in mouse and ferret. PLoS ONE. 2010; 5(3):e9812.

Sambhara S, Poland GA. H5N1 avian influenza: Preventive and therapeutic strategies against a pandemic. Annual Review of Medicine. 2010; 61:187-98.

Song J-M, Kim Y-C, Lipatov AS, Pearton M, Davis CT, Yoo D-G, Park K-M, Chen L-M, Quan F-S, Birchall JC, Donis RO, Prausnitz MR, Compans RW, Kang S-M. Microneedle delivery of H5N1 influenza virus-like particles to the skin induces long-lasting B- and T-Cell responses in mice. Clinical and Vaccine Immunology. 2010;17(9):1381-9.

Steitz J, Wagner RA, Bristol T, Gao W, Donis RO, Gambotto A. Route of administration and dose escalation assessment of an adenovirus-based influenza A (H5N1) vaccine in chickens. Clinical Vaccine Immunology. 2010; 17(9):1467-72.

Tolnay A-E, Baskin CR, Tumpey TM, Sabourin PJ, Sabourin CL, Long JP, Pyles JA, Albrecht RA, Garcia-Sastre A, Katze MG, Bielefeldt-Ohmann H. Extrapulmonary tissue responses in cynomolgus macaques (Macaca fascicularis) infected with highly pathogenic avian influenza A (H5N1) virus. Archives of Virology. 2010; 155(6):905-14.

Wei C-J, Boyington JC, Dai K, Houser KV, Pearce MB, Kong W-P, Yang Z-y, Tumpey TM, Nabel GJ. Cross-neutralization of 1918 and 2009 influenza viruses: Role of glycans in viral evolution and vaccine design. Science Translational Medicine. 2010;2(24):1-8.

Writing Committee for the Joint Technical consultation on Avian influenza at the Human-Animal Interface. FAO-OIE-WHO joint technical consultation on avian influenza at the

human-animal interface. Influenza and Other Respiratory Viruses. 2010; 4(S1):1-29.

Reeves PM, Smith SK, Olson VA, Thorne SH, Bornmann W, Damon IK, Kalman D. Variola and monkeypox viruses utilize conserved mechanisms of virion motility and release that depend on abl and SRC family tyrosine kinases. J Virol. 2011 Jan; 85(1):21-31. Epub 2010 Oct 20. PubMed PMID: 20962097; PubMed Central PMCID: PMC3014172.

Formenty P, Muntasir MO, Damon I, Chowdhary V, Opoka ML, Monimart C, Mutasim EM, Manuguerra JC, Davidson WB, Karem KL, Cabeza J, Wang S, Malik MR, Durand T, Khalid A, Rioton T, Kuong-Ruay A, Babiker AA, Karsani ME, Abdalla MS. Human monkeypox outbreak caused by novel virus belonging to Congo Basin clade, Sudan, 2005. Emerg Infect Dis. 2010 Oct; 16(10):1539-45. PubMed PMID: 20875278.

DeHaven BC, Girgis NM, Xiao Y, Hudson PN, Olson VA, Damon IK, Isaacs SN. Poxvirus complement control proteins are expressed on the cell surface through an intermolecular disulfide bridge with the viral A56 protein. J Virol. 2010 Nov; 84(21):11245-54. Epub 2010 Aug 18. PubMed PMID: 20719953; PubMed Central PMCID: PMC2953161.

Li Y, Zhao H, Wilkins K, Hughes C, Damon IK. Real-time PCR assays for the specific detection of monkeypox virus West African and Congo Basin strain DNA. J Virol Methods. 2010 Oct; 169(1):223-7. Epub 2010 Jul 17. PubMed PMID: 20643162.

McNulty S, Bornmann W, Schriewer J, Werner C, Smith SK, Olson VA, Damon IK, Buller RM, Heuser J, Kalman D. Multiple phosphatidylinositol 3-kinases regulate vaccinia virus morphogenesis. PLoS One. 2010 May 28; 5(5):e10884. PubMed PMID: 20526370; PubMed Central PMCID: PMC2878334.

Hutson CL, Carroll DS, Self J, Weiss S, Hughes CM, Braden Z, Olson VA, Smith SK, Karem KL, Regnery RL, Damon IK. Dosage comparison of Congo Basin and West African strains of monkeypox virus using a prairie dog animal model of systemic orthopoxvirus disease. Virology. 2010 Jun 20; 402(1):72-82. Epub 2010 Apr 5. PubMed PMID: 20374968.

Reynolds MG, Carroll DS, Olson VA, Hughes C, Galley J, Likos A, Montgomery JM, Suu-Ire R, Kwasi MO, Jeffrey Root J, Braden Z, Abel J, Clemmons C, Regnery R, Karem K, Damon IK. A silent enzootic of an orthopoxvirus in Ghana, West Africa: evidence for multi-species involvement in the absence of widespread human disease. Am J Trop Med Hyg. 2010 Apr; 82(4):746-54. PubMed PMID: 20348530; PubMed Central PMCID: PMC2844556.

Beesley, CA, Vanner CL, Helsel LO, Gee JE, Hoffmaster AR. Identification and Characterization of clinical *Bacillus* spp. isolates phenotypically similar to Bacillus anthracis. EMS Microbiol Lett 313:47-53.

Huang WT, Chang S, Miller ER, Jane Woo E, Hoffmaster AR, Gee JE, Clark TA, Iskander JK, Ball R, Broder KR. Safety assessment of recalled Haemophilus influenzae type b (Hib)

conjugate vaccines--United States, 2007-2008. Pharmacoepidemiol Drug Saf 19:306-10.

Lonsway, DR, Jevitt LA, Uhl JR, Cockerill FR 3rd, Anderson ME, Sullivan MM, De BK, Edwards JR, Patel JB. Effect of carbon dioxide on broth microdilution susceptibility testing of Brucella spp. J Clin Microbiol 48:952-6.

Mukhopadhyay S., Thomason MK, Lentz S, Nolan N, Willner K, Gee JE, Glass MB, Inglis TJ, Merritt A, Levy A, Sozhamannan S, Mateczun A, and Read TD. High-redundancy draft sequencing of 15 clinical and environmental *Burkholderia* strains. J Bacteriol 192:6313-4.

Pearson T, Giffard P, Beckstrom-Sternberg S, Auerbach R, Hornstra H, Tuanyok A, Price EP, Glass MB, Leadem B, Beckstrom-Sternberg JS, Allan GJ, Foster JT, Wagner DM, Okinaka RT, Sim SH, Pearson O, Wu Z, Chang J, Kaul R, Hoffmaster AR,. Brettin, TS Robison RA, Mayo M, Gee JE, Tan P, Currie BJ, and Keim P. 2009. Phylogeographic reconstruction of a bacterial species with high levels o lateral gene transfer. BMC Biol 7:78.

Scholz HC, Nockler K, Gollner C, Bahn P, Vergnaud G, Tomaso H, Al Dahouk S, Kampfer P, Cloeckaert A, Maquart M, Zygmunt MS, Whatmore AM, Pfeffer M, Huber B,. Busse HJ, and De BK. *Brucella inopinata* sp. nov., isolated from a breast implant infection. Int J Syst Evol Microbiol 60:801-8.

Sim BM, Chantratita N, Ooi WF, Nandi T, Tewhey R, Wuthiekanun V., Thaipadungpanit J, Tumapa S, Ariyaratne P, Sung WK, Sem XH, Chua HH, Ramnarayanan K, Lin CH, Liu Y, Feil EJ, Glass MB, Tan G, Peacock SJ, and Tan P. Genomic acquisition of a capsular polysaccharide virulence cluster by non-pathogenic*Burkholderia i*solates. Genome Biol 11:R89.

Tiller RV, Gee JE, Frace MA, Taylor TK, Setubal JC, Hoffmaster AR, and De BK. Characterization of novel *Brucella* strains originating from wild native rodent species In North Queensland, Australia. Appl Environ Microbiol 76:5837-45.

Tiller RV, Gee JE, Lonsway DR, Gribble S, Bell SC, Jennison AV, Bates J, Coulter C, Hoffmaster AR, and De BK. Identification of an unusual *Brucella* strain (BO2) from a lung biopsy in a 52 year-old patient with chronic destructive pneumonia. BMC Microbiol 10:23.

Winchell JM, Wolff BJ, Tiller R, Bowen MD, and Hoffmaster A R. Rapid identification and discrimination of *Brucella* isolates by use of real-time PCR and high-resolution melt analysis. J Clin Microbiol 48:697-702.

Clarisse AT, Anderson SM., Imholte SB., Erhart LM., Chen S, Park BJ., Christ C, Komatsu KK., Chiller T, and. Sunenshine RH. Enhanced Surveillance of Coccidioidomycosis, Arizona, USA, 2007-2008 Emerging Infectious Diseases. Vol. 16, No. 11, November 2010 1738-1744.

Wilder-Kofie T, Lúquez C, Adler M, Dykes J, Coleman J, Maslanka S. An Alternative In

Vivo Method to Refine the Mouse Bioassay for Botulinum Toxin Detection. Comparative Medicine. (2010, accepted)

Maslanka SE, Lúquez C, Raphael B, Dykes J, Joseph L. Utility of Botulinum Toxin ELISA A, B, E, and F kits for Clinical Laboratory Investigations of Human Botulism. The Botulinum Journal (2010, accepted)

Raphael B, Joseph L, McCroskey L, Lúquez C, Maslanka S. Detection and differentiation of *Clostridium botulinum* type A strains using a focused DNA microarray. Mol. Cell Probes. 2010. 24: 146-153.

Raphael B, Choudoir M, Lúquez C, Fernández R, Maslanka S. Sequence diversity of genes encoding botulinum neurotoxin type F. Appl Environ. Microbiol. 2010. 76: 4805-4812

Lúquez C, Dykes J, Yu P, Raphael B, Maslanka S. First report worldwide of an infant botulism case due to *Clostridium botulinum* type E. J Clin. Microbiol. 2010. 48: 326-328.

Hodges LR, Rose LJ, O'Connell H, Arduino MJ. National validation study of a swab protocol for the recovery *of Bacillus anthracis* spores from surfaces. *J Microbiol Methods* 2010; 81(2):141-6.

Létant SE, Kane SR, Murphy GA, Alfaro TM, Hodges LR, Rose LJ, Raber E. Most-probable-number rapid viability PCR method to detect viable spores of *Bacillus anthracis* in swab samples. *J Microbiol Methods* 2010; 81(2):200-2

Tiller RV, Gee JE, Lonsway DR, Gribble S, Bell SC, Jennison AV, Bates J, Coulter C, Hoffmaster AR, De BK. Identification of an unusual Brucella strain (BO2) from a lung biopsy in a 52 year-old patient with chronic destructive pneumonia.BMC Microbiol. 2010 Jan 27;10:23

Lonsway DR, Jevitt LA, Uhl JR, Cockerill FR 3rd, Anderson ME, Sullivan MM, De BK, Edwards JR, Patel JB. Effect of carbon dioxide on broth microdilution susceptibility testing of Brucella spp. J Clin Microbiol. 2010 Mar; 48(3):952-6. Epub 2009 Dec 23.

Weigel LM, Sue D, Michel PA, Kitchel B, aPillai SP. 2010. A rapid antimicrobial susceptibility test for Bacillus anthracis. Antimicrob Agents Chemother. 54(7):2793-800.

Stephens KW, Hutchins RJ. Dauphin LA. 2010. Cross-platform evaluation of commercial real-time reverse-transcription PCR master mixes using a 5' nuclease assay for Ebola virus. *Mol Cell Probes*. 24(6):370-75

Walker RE., Petersen JM, Stephens KW, Dauphin LA. 2010. Optimal swab processing recovery method for detection of bioterrorism-related Francisella tularensis by real-time PCR. *J Microbiol Methods*. 83(1):42-7

Dauphin LA, Stephens KW, Eufinger SC., Bowen MD. 2010. Comparison of five commercial DNA extraction kits for the recovery of DNA from *Yersinia pestis* suspensions and spiked environmental samples. *J Applied Microbiol*. 108(1):163-72

Stephens KW. Hutchins RJ. Dauphin LA. Cross-platform evaluation of commercial real-time reverse transcription PCR master mix kits using a quantitative 5â€²nuclease assay for Ebola virus. Molecular and Cellular Probes Volume 24, Issue 6, December 2010, Pages 370-375

Alzahrani AG, Al Shaiban HM, Al Mazroa MA, Al-Hayani O, MacNeil A, Rollin PE, Ziad AM, Ziad AA. Hemorrhagic Fever in Humans, Najran, Saudi Arabia. Emerging Infectious Diseases. 2010; 16(12):1882-1888

Amorosa V, MacNeil A, McConnell R, Patel A, Dillon KE, Hamilton K, Erickson BR, Campbell S, Knust B, Cannon D, Miller D, Manning C, Rollin PE, Nichol ST. Imported Lassa Fever, Pennsylvania, USA, 2010. Emerging Infectious Diseases. 2010; 16(10):1598-1600.

Andriamandimby SF, Randrianarivo-Solofoniaina AE, Jeanmaire EM, Ravololomanana L, Tiana RM, Lanto RT, Razainirina J, Hoffmann J, Ravalohery, Rafi sandratantsoa J; Rollin, PE, Reynes J. Rift Valley Fever during Rainy Seasons, Madagascar, 2008 and 2009. Emerging Infectious Diseases. 2010; 16(6):963-970.

Aradaib IE, Erickson BR, Mustafa ME, Khristova ML, Saeed NS, Elageb RM., Nichol, ST. Nosocomial outbreak of Crimean-Congo hemorrhagic fever, Sudan. Emerging Infectious Diseases. 2010; 16(5):837-839.

Bergeron E, Albarino CG,; Khristova ML, Nichol, ST. Crimean-Congo hemorrhagic fever virus-encoded ovarian tumor protease activity is dispensable for virus RNA polymerase function. Journal of Virology. 2010; 84(1):216-226.

Carroll SA, Bird BH, Rollin PE, and Nichol ST. Ancient common ancestry of Crimean-Congo hemorrhagic fever virus. Molecular Phylogenetics and Evolution. 2010; 55:1103-1110.

Centers for Disease Control and Prevention. Tick-borne encephalitis among US travelers to Europe and Asia 2000-2009. MMWR - Morbidity & Mortality Weekly Report. 2010; 59(11):335-338.

Chiang, C, Lo MK, Rota PA, Spiropoulou CF, Rollin PE. Use of monoclonal antibodies against Hendra and Nipah viruses in an antigen capture ELISA. Virology Journal. 2010; 7(1):115.

Gupta, M, Goldsmith CS, Metcalfe MG, Spipopoulou CF, Rollin PE. Reduced virus replication, proinflammatory cytokine production, and delayed macrophage cell death in

human PBMCs infected with the newly discovered Bundibugyo ebolavirus relative to Zaire ebolavirus. Virology. 2010; 402:203-208.

Hartman AL, Towner JS., Nichol ST. Ebola and marburg hemorrhagic fever. Clinics in Laboratory Medicine. 2010; 30 (1):161-177.

Hensley LE, Mulangu S, Asiedu C, Johnson J, Honko AN, Stanley D, Fabozzi G, Nichol ST, Ksiazek TG, Rollin PE, Wahl-Jensen V, Bailey M, Jahrling PB, Roederer M, Koup RA, Sullivan NJ. Demonstration of Cross-Protective Vaccine Immunity against an Emerging Pathogenic Ebolavirus Species. PloS Pathogens. 2010; 5(6):e1000904

Homaira N, Rahman Ma, Hossain M J,; Epstein JH, Sultana R, Khan MS, Podder G, Nahar K, Ahmed B, Gurley ES, Daszak PP. Nipah virus outbreak with person-to-person transmission in a district of Bangladesh, 2007. Epidemiology and Infection. 2010; 138(11):1630-1636.

Homaira N, Rahman M, Hossain MJ, Nahar N, Khan R, Rahma M, Podder G, Nahar K, Khan Da, Gurley ES, Rollin PE, Comer JA, Ksiazek TG, Luby SP. Cluster of Nipah virus infection, Kushtia District, Bangladesh, 2007. PLoS One. 2010; 5(10):e13570.

Kuhn JH, Becker S, Ebihara H, Geisbert TW, Johnson KM, Kawaoka,Y, Lipkin WI, Negredo AI, Netesov SV, Nichol ST, Palacios G, Peters CJ, Tenorio A, Volchkov VE, Jahrling PB. Proposal for a revised taxonomy of the family Filoviridae: classification, names of taxa and viruses, and virus abbreviations. Archives of Virology. 2010; 155(12):2083-2103.

Lo MK, Miller D, Aljofan M, Mungall BA, Rollin PE, Bellini WJ, and Rota PA. Characterization of the antiviral and inflammatory responses against Nipah virus in endothelial cells and neurons. 2010; 404, 78-88.

MacNeil A, Farnon EC, Wamala J, Okware S, Cannon DL, Reed Z, Towner JS, Tappero JW, Lutwama Ju, Downing R, Nichol ST, Ksiazek TG, Rollin PE. Proportion of Deaths and Clinical Features in Bundibugyo Ebola Virus Infection, Uganda. Emerging Infectious Diseases. 2010; 16(12).

Maltezou HC, Andonova L, Andraghetti R, Bouloy M, Ergonul O, Jongejan F, Kalvatchev N, Nichol S, Niedrig M, Platonov A, Thomson G, Leitmeyer K, Zeller H. Crimean-Congo hemorrhagic fever in Europe: current situation calls for preparedness. Euro Surveillance. 2010; 15(10):19504.

Yanni EA, Marano N, Han P, Edelson PJ, Blumensaadt S, Becker M, Dwyer S, Crocker K, Daley T, Davis X, Gallagher N, Balaban V, McCarron M, Mounts A, Lipman H, Brown C, Kozarsky P. Knowledge, attitudes, and practices of US travelers to Asia regarding seasonal influenza and H5N1 avian influenza prevention measures. Journal of Travel Medicine.

2010; 17(6):374-81.

Ake JA, Massung RF, Whitman TJ, Gleeson TD. Difficulties in the diagnosis and management of a US servicemember presenting with possible chronic Q fever. Journal of Infection 60(2):175-177. 2010.

Amitai,Z, Bromberg M, Bernstein M, Raveh D, Keysary A, David D, Pitlik S, Swerdlow D, Massung R, Rzotkiewicz S, Halutz O, Shohat T. A large Q fever outbreak in an urban school in central Israel. Clinical Infectious Diseases 2010 June 1; 50(11):1433-1438.

Anderson AD, Baker TR, Littrell AC, Mott RL, Niebuhr DW, Smoak BL. A seroepidemiologic survey for Coxiella burnetii among hospitalized U.S. troops deployed to Iraq. Zoonoses Public Health. 2010 Sep 29. doi: 10.1111/j.1863-2378.2010.01347.x.

Kersh G J, Lambourn DM, Self JS, Akmajian AM, Stanton JB, Baszler TV, Raverty SA, Massung RF. Coxiella burnetii infection of a Steller sea lion (Eumetopias jubatus) found in Washington State. Journal of Clinical Microbiology 2010; 48(9):3428-3431.

Kersh GJ, Wolfe TM, Fitzpatrick KA, Candee AJ, Oliver LD, Patterson NE, Self JS, Priestley RA, Loftis AD, Massung RF. Presence of Coxiella burnetii DNA in the environment of the United States, 2006 to 2008. Applied and Environmental Microbiology 2010 Jul; 76(13):4469-4475.

Loftis A D, Priestley RA, Massung RF. Detection of Coxiella burnetii in commercially available raw milk from the United States. Foodborne Pathogens and Disease 2010 Dec; 7(12):1453-1456.

Miceli MH, Veryser AK, Anderson AD, Hofinger D, Lee SA, Tancik C. A case of person-to-person transmission of Q fever from an active duty serviceman to his spouse. Vector Borne and Zoonotic Diseases 2010 Jun; 10(5):539-541.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
Activities include developing diagnostic assayss for public health, conducting molecular and antigenic characterization of microorganisms, evaluating decontamination methods, determining pathogenicity and virulence of infectious agents, determining the natural history of infectious organisms, and conducting epidemiologic studies and surveillance for diseases. Biodefense activities include those with select agents.
The select agents list is available at:
http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html

[*] Including viruses and prions

Additional information can be found at:
http://emergency.cdc.gov/labissues/
http://www.cdc.gov/fmo/topic/Budget%20Information/CIO_Overviews/cio_overviews_pdf/CCID.pdf
http://www.federallabs.org/labs/profile/?Agency=26&id=1884

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category A, B and C Priority Pathogens
- **Overlap Select Agents**
  Including NIAID Category A, B and C Priority Pathogens
- **USDA Select Agents and Toxins**
  Including NIAID Category A Priority Pathogens
- **Other pathogens or toxins**
  Including non-Select Agent, NIAID Category A and C Priority Pathogens

III. Outdoor Studies:
None

Form A, Part 2 (iii)

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

NIH, C.W. Bill Young Center for Biodefense and Emerging Infectious Diseases

2. Where is it located (provide both address and geographical location)?

National Institutes of Health (NIH)
U.S. Department of Health and Human Services
9000 Rockville Pike
Bethesda, Maryland 20892

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	2493
BL3 (sqM)	1091
BL4 (sqM)	0
Total (sqM)	3584

4. The organizational structure of each facility.

I Total Number of Personnel 118

II Division of Personnel:

Military	0
Civilian	118

III Division of Personnel by Category:

Scientists	95
Engineers	0
Technicians	23
Administrative/Support	0

IV List the scientific disciplines represented in the scientific/engineering support staff.

Bacteriology
Biology
Chemistry
Medicine

Pathogenesis
Virology

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 12

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Health and Human Services (HHS)

VII What are the funding levels for the following program areas:

Research	$38,735,010
Development	$ 0
Test and evaluation	$ 0
Total	$38,735,010

VIII Briefly describe the publication policy of the facility:

All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (http://publicaccess.nih.gov/policy.htm) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National Library of Medicine's digital archive PubMed Central upon acceptance for publication. To help advance science and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Goldszmid RS, Sher A. Processing and presentation of antigens derived from intracellular protozoan parasites. Curr Opin Immunol. 2010 Feb; 22(1):118-23. Epub 2010 Feb 10. Review. PubMed PMID: 20153156; PubMed Central PMCID: PMC2871680.

Mayer-Barber KD, Barber DL, Shenderov K, White SD, Wilson MS, Cheever A, Kugler D, Hieny S, Caspar P, Núñez G, Schlueter D, Flavell RA, Sutterwala FS, Sher A. Caspase-1 independent IL-1beta production is critical for host resistance to mycobacterium tuberculosis and does not require TLR signaling in vivo. J Immunol. 2010 Apr 1; 184(7):3326-30. Epub 2010 Mar 3. PubMed PMID: 20200276.

Min-Oo G, Ayi K, Bongfen SE, Tam M, Radovanovic I, Gauthier S, Santiago H, Rothfuchs

AG, Roffê E, Sher A, Mullick A, Fortin A, Stevenson MM, Kain KC, Gros P. Cysteamine, the natural metabolite of pantetheinase, shows specific activity against Plasmodium. Exp Parasitol. 2010 Aug; 125(4):315-24. Epub 2010 Feb 26. PubMed PMID: 20219464.

Wilson MS, Feng CG, Barber DL, Yarovinsky F, Cheever AW, Sher A, Grigg M, Collins M, Fouser L, Wynn TA. Redundant and pathogenic roles for IL-22 in mycobacterial, protozoan, and helminth infections. J Immunol. 2010 Apr 15; 184(8):4378-90. Epub 2010 Mar 10. PubMed PMID: 20220096.

Antonelli LR, Gigliotti Rothfuchs A, Gonçalves R, Roffê E, Cheever AW, Bafica A, Salazar AM, Feng CG, Sher A. Intranasal Poly-IC treatment exacerbates tuberculosis in mice through the pulmonary recruitment of a pathogen-permissive monocyte/macrophage population. J Clin Invest. 2010 May 3;120(5):1674-82. doi: 10.1172/JCI40817. Epub 2010 Apr 12. PubMed PMID: 20389020; PubMed Central PMCID: PMC2860920.

Barber DL, Mayer-Barber KD, Antonelli LR, Wilson MS, White S, Caspar P, Hieny S, Sereti I, Sher A. Th1-driven immune reconstitution disease in Mycobacterium avium-infected mice. Blood. 2010 Nov 4; 116(18):3485-93. Epub 2010 Jul 23. PubMed PMID: 20656932; PubMed Central PMCID: PMC2981475.

Antonelli LR, Mahnke Y, Hodge JN, Porter BO, Barber DL, DerSimonian R, Greenwald JH, Roby G, Mican J, Sher A, Roederer M, Sereti I. Elevated frequencies of highly activated CD4+ T cells in HIV+ patients developing immune reconstitution inflammatory syndrome. Blood. 2010 Nov 11; 116(19):3818-27. Epub 2010 Jul 26. PubMed PMID: 20660788; PubMed Central PMCID: PMC2981537.

Coffman RL, Sher A, Seder RA. Vaccine adjuvants: putting innate immunity to work. Immunity. 2010 Oct 29; 33(4):492-503. Review. PubMed PMID: 21029960.

Walseng E, Furuta K, Goldszmid RS, Weih KA, Sher A, Roche PA. Dendritic cell activation prevents MHC class II ubiquitination and promotes MHC class II survival regardless of the activation stimulus. J Biol Chem. 2010 Dec 31;285(53):41749-54. Epub 2010 Nov 3. PubMed PMID: 21047782; PubMed Central PMCID: PMC3009902.

Feng CG, Sher A. Parasites paralyze cellular host defense system to promote virulence. Cell Host Microbe. 2010 Dec 16; 8(6):463-4. PubMed PMID: 21147459; PubMed Central PMCID: PMC3016946.

Shamputa IC, Lee J, Allix-Béguec C, Cho EJ, Lee JI, Rajan V, Lee EG, Min JH, Carroll MW, Goldfeder LC, Kim JH, Kang HS, Hwang S, Eum SY, Park SK, Lee H, Supply P, Cho SN, Via LE, Barry CE 3rd. Genetic diversity of Mycobacterium tuberculosis isolates from a tertiary care tuberculosis hospital in South Korea. J Clin Microbiol. 2010 Feb;48(2):387-94. Epub 2009 Dec 16. PubMed PMID: 20018816; PubMed Central PMCID: PMC2815581.

Eum SY, Kong JH, Hong MS, Lee YJ, Kim JH, Hwang SH, Cho SN, Via LE, Barry CE 3rd.

Neutrophils are the predominant infected phagocytic cells in the airways of patients with active pulmonary TB. Chest. 2010 Jan; 137(1):122-8. Epub 2009 Sep 11. PubMed PMID: 19749004; PubMed Central PMCID: PMC2803122.

Via LE, Cho SN, Hwang S, Bang H, Park SK, Kang HS, Jeon D, Min SY, Oh T, Kim Y, Kim YM, Rajan V, Wong SY, Shamputa IC, Carroll M, Goldfeder L, Lee SA, Holland SM, Eum S, Lee H, Barry CE 3rd. Polymorphisms associated with resistance and cross-resistance to aminoglycosides and capreomycin in Mycobacterium tuberculosis isolates from South Korean Patients with drug-resistant tuberculosis. J Clin Microbiol. 2010 Feb; 48(2):402-11. Epub 2009 Dec 23. PubMed PMID: 20032248; PubMed Central PMCID: PMC2815586.

Singh R, Barry CE 3rd, Boshoff HI. The three RelE homologs of Mycobacterium tuberculosis have individual, drug-specific effects on bacterial antibiotic tolerance. J Bacteriol. 2010 Mar; 192(5):1279-91. Epub 2010 Jan 8. PubMed PMID: 20061486; PubMed Central PMCID: PMC2820853.

Watrous J, Burns K, Liu WT, Patel A, Hook V, Bafna V, Barry CE 3rd, Bark S, Dorrestein PC. Expansion of the mycobacterial "PUPylome". Mol Biosyst. 2010 Feb;6(2):376-85. Epub 2009 Nov 16. PubMed PMID: 20094657; PubMed Central PMCID: PMC2846642.

Motiwala AS, Dai Y, Jones-López, EC, Hwang SH, Lee JS, Cho SN, Via LE, Barry CE, Alland D. Mutations in extensively drug-resistant Mycobacterium tuberculosis that do not code for known drug-resistance mechanisms. J Infect Dis. 2010 Mar15; 201(6):881-8. PubMed PMID: 20136412; PubMed Central PMCID: PMC2826498.

Eum SY, Lee YJ, Min JH, Kwak HK, Hong MS, Kong JH, Hwang SH, Park SK, Leblanc JJ, Via LE, Barry CE 3rd, Cho SN. Association of antigen-stimulated release of tumor necrosis factor-alpha in whole blood with response to chemotherapy in patients with pulmonary multidrug-resistant tuberculosis. Respiration. 2010; 80(4):275-84. Epub 2010 Feb 10. PubMed PMID: 20145387; PubMed Central PMCID: PMC2955738.

Dartois V, Barry CE. Clinical pharmacology and lesion penetrating properties of second- and third-line antituberculous agents used in the management of multidrug-resistant (MDR) and extensively-drug resistant (XDR) tuberculosis. Curr Clin Pharmacol. 2010 May 1; 5(2):96-114. Review. PubMed PMID: 20156156.

Kastrinsky DB, Barry CE. Synthesis of labeled meropenem for the analysis of M. tuberculosis transpeptidases. Tetrahedron Lett. 2010; 51(1):197-200. PubMed PMID: 20161438; PubMed Central PMCID: PMC2789577.

Barry CE 3rd, Blanchard JS. The chemical biology of new drugs in the development for tuberculosis. Curr Opin Chem Biol. 2010 Aug; 14(4):456-66. Epub 2010 May 7. Review. PubMed PMID: 20452813; PubMed Central PMCID: PMC2918717.

Russell DG, Barry CE 3rd, Flynn JL. Tuberculosis: what we don't know can, and does, hurt

us. Science. 2010 May 14; 328(5980):852-6. Review. PubMed PMID: 20466922; PubMed Central PMCID: PMC2872107.

Donald PR, Marais BJ, Barry CE 3rd. Age and the epidemiology and pathogenesis of tuberculosis. Lancet. 2010 May 29; 375(9729):1852-4. Epub 2010 May 18. PubMed PMID: 20488519.

Bollo S, Núñez-Vergara LJ, Kang S, Zhang L, Boshoff HI, Barry CE 3rd, Squella JA, Dowd CS. The effect of 5-substitution on the electrochemical behavior andantitubercular activity of PA-824. Bioorg Med Chem Lett. 2011 Jan 15; 21(2):812-7. Epub 2010 Nov 25. PubMed PMID: 21168331; PubMed Central PMCID: PMC3021465.

Chakravorty S, Aladegbami B, Thoms K, Lee JS, Lee EG, Rajan V, Cho EJ, Kim H, Kwak H, Kurepina N, Cho SN, Kreiswirth B, Via LE, Barry CE 3rd, Alland D. Rapid detection of fluoroquinolone-resistant and hetero-resistant Mycobacterium tuberculosis using sloppy molecular beacons and a dual melting temperature code in a real-time PCR assay. J Clin Microbiol. 2010 Dec 29. [Epub ahead of print] PubMed PMID: 21191047.

Kuhn JH, Jahrling PB. Clarification and guidance on the proper usage of virus and virus species names. Arch Virol. 2010 Apr; 155(4):445-53. Epub 2010 Mar 4. Review. PubMed PMID: 20204430; PubMed Central PMCID: PMC2878132.

Hensley LE, Mulangu S, Asiedu C, Johnson J, Honko AN, Stanley D, Fabozzi G, Nichol ST, Ksiazek TG, Rollin PE, Wahl-Jensen V, Bailey M, Jahrling PB, Roederer M, Koup RA, Sullivan NJ. Demonstration of cross-protective vaccine immunity against an emerging pathogenic Ebolavirus Species. PLoS Pathog. 2010 May 20; 6(5):e1000904. PubMed PMID: 20502688; PubMed Central PMCID: PMC2873919.

Geisbert TW, Bailey M, Geisbert JB, Asiedu C, Roederer M, Grazia-Pau M, Custers J, Jahrling P, Goudsmit J, Koup R, Sullivan NJ. Vector choice determines immunogenicity and potency of genetic vaccines against Angola Marburg virus in nonhuman primates. J Virol. 2010 Oct;84(19):10386-94. Epub 2010 Jul 21. PubMed PMID: 20660192; PubMed Central PMCID: PMC2937810.

Van Regenmortel MH, Burke DS, Calisher CH, Dietzgen RG, Fauquet CM, Ghabrial SA, Jahrling PB, Johnson KM, Holbrook MR, Horzinek MC, Keil GM, Kuhn JH, Mahy BW,Martelli GP, Pringle C, Rybicki EP, Skern T, Tesh RB, Wahl-Jensen V, Walker PJ,Weaver SC. A proposal to change existing virus species names to non-Latinized binomials. Arch Virol. 2010 Nov; 155(11):1909-19. Epub 2010 Oct 16. PubMed PMID: 20953644.

Kuhn JH, Becker S, Ebihara H, Geisbert TW, Johnson KM, Kawaoka Y, Lipkin WI, Negredo AI, Netesov SV, Nichol ST, Palacios G, Peters CJ, Tenorio A, Volchkov VE,Jahrling PB. Proposal for a revised taxonomy of the family Filoviridae: classification, names of taxa and viruses, and virus abbreviations. Arch Virol. 2010 Dec; 155(12):2083-

103. Epub 2010 Oct 30. PubMed PMID: 21046175.

Johnson RF, Dyall J, Ragland DR, Huzella L, Byrum R, Jett C, St Claire M, Smith AL, Paragas J, Blaney JE, Jahrling PB. Comparative analysis of monkeypox virus infection of cynomolgus macaques by the intravenous or intrabronchial inoculation route. J Virol. 2011 Mar; 85(5):2112-25. Epub 2010 Dec 8. PubMed PMID: 21147922.

Alfano RW, Leppla SH, Liu S, Bugge TH, Ortiz JM, Lairmore TC, Duesbery NS, Mitchell IC, Nwariaku F, Frankel AE. Inhibition of tumor angiogenesis by the matrix metalloproteinase-activated anthrax lethal toxin in an orthotopic model of anaplastic thyroid carcinoma. Mol Cancer Ther. 2010 Jan; 9(1):190-201. Epub 2010 Jan 6. PubMed PMID: 20053778; PubMed Central PMCID: PMC2806504.

Gupta PK, Liu S, Leppla SH. Characterization of a Chinese hamster ovary cell mutant having a mutation in elongation factor-2. PLoS One. 2010 Feb 5; 5(2):e9078. PubMed PMID: 20140093; PubMed Central PMCID: PMC2816718.

Connolly BM, Choi EY, Gårdsvoll H, Bey AL, Currie BM, Chavakis T, Liu S, Molinolo A, Ploug M, Leppla SH, Bugge TH. Selective abrogation of the uPA-uPAR interaction in vivo reveals a novel role in suppression of fibrin-associated inflammation. Blood. 2010 Sep 2; 116(9):1593-603. Epub 2010 May 13. PubMed PMID: 20466854; PubMed Central PMCID: PMC2938846.

Newman ZL, Printz MP, Liu S, Crown D, Breen L, Miller-Randolph S, Flodman P, Leppla SH, Moayeri M. Susceptibility to anthrax lethal toxin-induced rat death is controlled by a single chromosome 10 locus that includes rNlrp1. PLoS Pathog. 2010 May 20;6(5):e1000906. PubMed PMID: 20502689; PubMed Central PMCID: PMC2873920.

Newman ZL, Crown D, Leppla SH, Moayeri M. Anthrax lethal toxin activates the inflammasome in sensitive rat macrophages. Biochem Biophys Res Commun. 2010 Aug 6;398(4):785-9. Epub 2010 Jul 16. PubMed PMID: 20638366; PubMed Central PMCID: PMC2925535.

Sastalla I, Rosovitz MJ, Leppla SH. Accidental selection and intentional restoration of sporulation-deficient Bacillus anthracis mutants. Appl Environ Microbiol. 2010 Sep; 76(18):6318-21. Epub 2010 Jul 16. PubMed PMID: 20639373; PubMed Central PMCID: PMC2937495.

Radjainia M, Hyun JK, Leysath CE, Leppla SH, Mitra AK. Anthrax toxin-neutralizing antibody reconfigures the protective antigen heptamer into a supercomplex. Proc Natl Acad Sci U S A. 2010 Aug 10; 107(32):14070-4. Epub 2010 Jul 26. PubMed PMID: 20660775; PubMed Central PMCID: PMC2922573.

Sastalla I, Maltese LM, Pomerantseva OM, Pomerantsev AP, Keane-Myers A, Leppla SH. Activation of the latent PlcR regulon in Bacillus anthracis. Microbiology. 2010 Oct;156(Pt

10):2982-93. Epub 2010 Aug 5. PubMed PMID: 20688829.

Jiao GS, Kim S, Moayeri M, Cregar-Hernandez L, McKasson L, Margosiak SA, Leppla SH, Johnson AT. Antidotes to anthrax lethal factor intoxication. Part 1: Discovery of potent lethal factor inhibitors with in vivo efficacy. Bioorg Med Chem Lett. 2010 Nov 15;20(22):6850-3. Epub 2010 Aug 15. PubMed PMID: 20864339; PubMed Central PMCID: PMC2965585.

Duverger A, Carré JM, Jee J, Leppla SH, Cormet-Boyaka E, Tang WJ, Tomé D, Boyaka PN. Contributions of edema factor and protective antigen to the induction of protective immunity by Bacillus anthracis edema toxin as an intranasal adjuvant. J Immunol. 2010 Nov 15; 185(10):5943-52. Epub 2010 Oct 15. PubMed PMID: 20952678.

Wycoff KL, Belle A, Deppe D, Schaefer L, Maclean JM, Haase S, Trilling AK, Liu S, Leppla SH, Geren IN, Pawlik J, Peterson JW. Recombinant anthrax toxin receptor-Fc fusion proteins produced in plants protect rabbits against inhalational anthrax. Antimicrob Agents Chemother. 2011 Jan; 55(1):132-9. Epub 2010 Oct 18. PubMed PMID: 20956592; PubMed Central PMCID: PMC3019684.

Okugawa S, Moayeri M, Eckhaus MA, Crown D, Miller-Randolph S, Liu S, Akira S, Leppla SH. MyD88-dependent signaling protects against anthrax lethal toxin-induced impairment of intestinal barrier function. Infect Immun. 2011 Jan; 79(1):118-24. Epub 2010 Oct 25. PubMed PMID: 20974827; PubMed Central PMCID: PMC3019866.

Liu S, Miller-Randolph S, Crown D, Moayeri M, Sastalla I, Okugawa S, Leppla SH. Anthrax toxin targeting of myeloid cells through the CMG2 receptor is essential for establishment of Bacillus anthracis infections in mice. Cell Host Microbe. 2010 Nov 18; 8(5):455-62. PubMed PMID: 21075356; PubMed Central PMCID: PMC3032408.

Newman ZL, Sirianni N, Mawhinney C, Lee MS, Leppla SH, Moayeri M, Johansen LM. Auranofin protects against anthrax lethal toxin-induced Nlrp1b-inflammasome activation. Antimicrob Agents Chemother. 2010 Dec 13. [Epub ahead of print] PubMed PMID: 21149629.

Moayeri M, Crown D, Newman ZL, Okugawa S, Eckhaus M, Cataisson C, Liu S, Sastalla I, Leppla SH. Inflammasome sensor Nlrp1b-dependent resistance to anthrax is mediated by caspase-1, IL-1 signaling and neutrophil recruitment. PLoS Pathog. 2010 Dec 9; 6(12):e1001222. PubMed PMID: 21170303; PubMed Central PMCID: PMC3000361.

Chen Z, Schneerson R, Lovchik J, Lyons CR, Zhao H, Dai Z, Kubler-Kielb J, Leppla SH, Purcell RH. Pre- and postexposure protection against virulent anthrax infection in mice by humanized monoclonal antibodies to Bacillus anthracis capsule. Proc Natl Acad Sci U S A. 2011 Jan 11; 108(2):739-44. Epub 2010 Dec 27. PubMed PMID: 21187383; PubMed Central PMCID: PMC3021070. Geisbert TW, Bailey M, Geisbert JB, Asiedu C, Roederer M, Grazia-Pau M, Custers J, Jahrling P, Goudsmit J, Koup R, Sullivan NJ. Vector choice

determines immunogenicity and potency of genetic vaccines against Angola Marburg virus in nonhuman primates. J Virol. 2010 Oct;84(19):10386-94. Epub 2010 Jul 21. PubMed PMID: 20660192; PubMed Central PMCID: PMC2937810.

Koonin EV, Moss B. Viruses know more than one way to don a cap. Proc Natl Acad Sci U S A. 2010 Feb 23; 107(8):3283-4. Epub 2010 Feb 18. PubMed PMID: 20167804; PubMed Central PMCID: PMC2840466.

Howard AR, Weisberg AS, Moss B. Congregation of orthopoxvirus virions in cytoplasmic A-type inclusions is mediated by interactions of a bridging protein (A26p) with a matrix protein (ATIp) and a virion membrane-associated protein (A27p). J Virol. 2010 Aug; 84(15):7592-602. Epub 2010 May 19. PubMed PMID: 20484506; PubMed Central PMCID: PMC2897617.

Americo JL, Moss B, Earl PL. Identification of wild-derived inbred mouse strains highly susceptible to monkeypox virus infection for use as small animal models. J Virol. 2010 Aug;84(16):8172-80. Epub 2010 Jun 2. PubMed PMID: 20519404;PubMed Central PMCID: PMC2916512.

Yang Z, Bruno DP, Martens CA, Porcella SF, Moss B. Simultaneous high-resolution analysis of vaccinia virus and host cell transcriptomes by deep RNA sequencing. Proc Natl Acad Sci U S A. 2010 Jun 22; 107(25):11513-8. Epub 2010 Jun 7. PubMed PMID: 20534518; PubMed Central PMCID: PMC2895082.

Shinoda K, Wyatt LS, Moss B. The neutralizing antibody response to the vaccinia virus A28 protein is specifically enhanced by its association with the H2 protein. Virology. 2010 Sep 15;405(1):41-9. Epub 2010 Jun 17. PubMed PMID: 20673745; PubMed Central PMCID: PMC2914698.

Kannanganat S, Nigam P, Velu V, Earl PL, Lai L, Chennareddi L, Lawson B, Wilson RL, Montefiori DC, Kozlowski PA, Moss B, Robinson HL, Amara RR. Preexisting vaccinia virus immunity decreases SIV-specific cellular immunity but does not diminish humoral immunity and efficacy of a DNA/MVA vaccine. J Immunol. 2010 Dec 15;185(12):7262-73. Epub 2010 Nov 12. PubMed PMID: 21076059.

Currier JR, Ngauy V, de Souza MS, Ratto-Kim S, Cox JH, Polonis VR, Earl P, Moss B, Peel S, Slike B, Sriplienchan S, Thongcharoen P, Paris RM, Robb ML, Kim J, Michael NL, Marovich MA. Phase I safety and immunogenicity evaluation of MVA-CMDR, a multigenic, recombinant modified vaccinia Ankara-HIV-1 vaccine candidate. PLoS One. 2010 Nov 15; 5(11):e13983. PubMed PMID: 21085591; PubMed Central PMCID: PMC2981570.

Pierson TC. Modeling antibody-enhanced dengue virus infection and disease in mice: protection or pathogenesis? Cell Host Microbe. 2010 Feb 18; 7(2):85-6. PubMed PMID:

20159612.

Sukupolvi-Petty S, Austin SK, Engle M, Brien JD, Dowd KA, Williams KL, Johnson S, Rico-Hesse R, Harris E, Pierson TC, Fremont DH, Diamond MS. Structure and function analysis of therapeutic monoclonal antibodies against dengue virus type 2. J Virol. 2010 Sep; 84(18):9227-39. Epub 2010 Jun 30. PubMed PMID: 20592088; PubMed Central PMCID: PMC2937608.

Fuchs A, Lin TY, Beasley DW, Stover CM, Schwaeble WJ, Pierson TC, Diamond MS. Direct complement restriction of flavivirus infection requires glycan recognition by mannose-binding lectin. Cell Host Microbe. 2010 Aug 19;8(2):186-95. PubMed PMID: 20709295; PubMed Central PMCID: PMC2929649.

Daffis S, Szretter KJ, Schriewer J, Li J, Youn S, Errett J, Lin TY, Schneller S, Zust R, Dong H, Thiel V, Sen GC, Fensterl V, Klimstra WB, Pierson TC, Buller RM, Gale M Jr, Shi PY, Diamond MS. 2'-O methylation of the viral mRNA cap evades host restriction by IFIT family members. Nature. 2010 Nov 18; 468(7322):452-6. PubMed PMID: 21085181.

Engel AR, Rumyantsev AA, Maximova OA, Speicher JM, Heiss B, Murphy BR, Pletnev AG. The neurovirulence and neuroinvasiveness of chimeric tick-borne encephalitis/dengue virus can be attenuated by introducing defined mutations into the envelope and NS5 protein genes and the 3' non-coding region of the genome. Virology. 2010 Sep 15;405(1):243-52. Epub 2010 Jul 1. PubMed PMID: 20594569; PubMed Central PMCID: PMC2914112.

Maximova OA, Murphy BR, Pletnev AG. High-throughput automated image analysis of neuroinflammation and neurodegeneration enables quantitative assessment of virus neurovirulence. Vaccine. 2010 Dec 6; 28(52):8315-26. Epub 2010 Aug 3. PubMed PMID: 20688036; PubMed Central PMCID: PMC2997939.

Heiss BL, Maximova OA, Pletnev AG. Insertion of microRNA targets into the flavivirus genome alters its highly neurovirulent phenotype. J Virol. 2011 Feb; 85(4):1464-72. Epub 2010 Dec 1. PubMed PMID: 21123372.

Lim JK, Obara CJ, Rivollier A, Pletnev AG, Kelsall BL, Murphy PM. Chemokine receptor Ccr2 is critical for monocyte accumulation and survival in West Nile virus encephalitis. J Immunol. 2011 Jan 1; 186(1):471-8. Epub 2010 Dec 3. PubMed PMID: 21131425.

Engel AR, Mitzel DN, Hanson CT, Wolfinbarger JB, Bloom ME, Pletnev AG. Chimeric Tick-Borne Encephalitis/Dengue Virus Is Attenuated in Ixodes scapularis Ticks and Aedes aegypti Mosquitoes. Vector Borne Zoonotic Dis. 2010 Dec 13. [Epub ahead of print] PubMed PMID: 21142950.

Schwartz JA, Buonocore L, Suguitan AL Jr, Silaghi A, Kobasa D, Kobinger G, Feldmann H, Subbarao K, Rose JK. Potent vesicular stomatitis virus-based avian influenza vaccines provide long-term sterilizing immunity against heterologous challenge. J Virol. 2010 May;

84(9):4611-8. Epub 2010 Feb 24. PubMed PMID: 20181720; PubMed Central PMCID: PMC2863739.

Min JY, Subbarao K. Cellular targets for influenza drugs. Nat Biotechnol. 2010 Mar; 28(3):239-40. PubMed PMID: 20212486.

Frieman MB, Chen J, Morrison TE, Whitmore A, Funkhouser W, Ward JM, Lamirande EW, Roberts A, Heise M, Subbarao K, Baric RS. SARS-CoV pathogenesis is regulated by a STAT1 dependent but a type I, II and III interferon receptor independent mechanism. PLoS Pathog. 2010 Apr 8; 6(4):e1000849. PubMed PMID: 20386712; PubMed Central PMCID: PMC2851658.

Corti D, Suguitan AL Jr, Pinna D, Silacci C, Fernandez-Rodriguez BM, Vanzetta F, Santos C, Luke CJ, Torres-Velez FJ, Temperton NJ, Weiss RA, Sallusto F, Subbarao K, Lanzavecchia A. Heterosubtypic neutralizing antibodies are produced by individuals immunized with a seasonal influenza vaccine. J Clin Invest. 2010 May 3; 120(5):1663-73. doi: 10.1172/JCI41902. Epub 2010 Apr 12. PubMed PMID: 20389023; PubMed Central PMCID: PMC2860935.

Wang W, Lu B, Zhou H, Suguitan AL Jr, Cheng X, Subbarao K, Kemble G, Jin H. Glycosylation at 158N of the hemagglutinin protein and receptor binding specificity synergistically affect the antigenicity and immunogenicity of a live attenuated H5N1 A/Vietnam/1203/2004 vaccine virus in ferrets. J Virol. 2010 Jul; 84(13):6570-7. Epub 2010 Apr 28. PubMed PMID: 20427525; PubMed Central PMCID: PMC2903256.

Madore DV, Meade BD, Rubin F, Deal C, Lynn F; Meeting Contributors. Utilization of serologic assays to support efficacy of vaccines in nonclinical and clinical trials: meeting at the crossroads. Vaccine. 2010 Jun 23; 28(29):4539-47. Epub 2010 May 12. PubMed PMID: 20470795; PubMed Central PMCID: PMC2886496.

Chen GL, Lamirande EW, Yang CF, Jin H, Kemble G, Subbarao K. Evaluation of replication and cross-reactive antibody responses of H2 subtype influenza viruses in mice and ferrets. J Virol. 2010 Aug; 84(15):7695-702. Epub 2010 May 26. PubMed PMID: 20504935; PubMed Central PMCID: PMC2897620.

Lau YF, Tang LH, McCall AW, Ooi EE, Subbarao K. An adjuvant for the induction of potent, protective humoral responses to an H5N1 influenza virus vaccine with antigen-sparing effect in mice. J Virol. 2010 Sep; 84(17):8639-49. Epub 2010 Jun 10. PubMed PMID: 20538850; PubMed Central PMCID: PMC2919013.

Graef KM, Vreede FT, Lau YF, McCall AW, Carr SM, Subbarao K, Fodor E. The PB2 subunit of the influenza virus RNA polymerase affects virulence by interacting with the mitochondrial antiviral signaling protein and inhibiting expression of beta interferon. J Virol. 2010 Sep; 84(17):8433-45. Epub 2010 Jun 10. PubMed PMID: 20538852; PubMed Central

PMCID: PMC2919034.

Lau YF, Tang LH, Ooi EE, Subbarao K. Activation of the innate immune system provides broad-spectrum protection against influenza A viruses with pandemic potential in mice. Virology. 2010 Oct 10; 406(1):80-7. Epub 2010 Jul 27. PubMed PMID: 20667572; PubMed Central PMCID: PMC2932846.

Min JY, Vogel L, Matsuoka Y, Lu B, Swayne D, Jin H, Kemble G, Subbarao K. Alive attenuated H7N7 candidate vaccine virus induces neutralizing antibody that confers protection from challenge in mice, ferrets, and monkeys. J Virol. 2010 Nov; 84(22):11950-60. Epub 2010 Sep 1. PubMed PMID: 20810733; PubMed Central PMCID: PMC2977864.

Roberts A, Lamirande EW, Vogel L, Baras B, Goossens G, Knott I, Chen J, Ward JM, Vassilev V, Subbarao K. Immunogenicity and protective efficacy in mice and hamsters of a Î²-propiolactone inactivated whole virus SARS-CoV vaccine. Viral Immunol. 2010 Oct;23(5):509-19. PubMed PMID: 20883165; PubMed Central PMCID: PMC2967819.

Min JY, Chen GL, Santos C, Lamirande EW, Matsuoka Y, Subbarao K. Classical swine H1N1 influenza viruses confer cross protection from swine-origin 2009 pandemic H1N1 influenza virus infection in mice and ferrets. Virology. 2010 Dec 5; 408(1):128-33. PubMed PMID: 20926110.

Lau YF, Santos C, Torres-Vélez FJ, Subbarao K. The magnitude of local immunity in the lungs of mice induced by live attenuated influenza vaccines is determined by local viral replication and induction of cytokines. J Virol. 2011 Jan;85(1):76-85. Epub 2010 Oct 20. PubMed PMID: 20962087; PubMed Central PMCID: PMC3014215.

Morens DM, Taubenberger JK, Harvey HA, Memoli MJ. The 1918 influenza pandemic: lessons for 2009 and the future. Crit Care Med. 2010 Apr; 38(4 Suppl):e10-20. Review. PubMed PMID: 20048675.

Gill JR, Sheng ZM, Ely SF, Guinee DG, Beasley MB, Suh J, Deshpande C, Mollura DJ, Morens DM, Bray M, Travis WD, Taubenberger JK. Pulmonary pathologic findings of fatal 2009 pandemic influenza A/H1N1 viral infections. Arch Pathol Lab Med. 2010 Feb; 134(2):235-43. PubMed PMID: 20121613; PubMed Central PMCID: PMC2819217.

Memoli MJ, Hrabal RJ, Hassantoufighi A, Eichelberger MC, Taubenberger JK. Rapid selection of oseltamivir- and peramivir-resistant pandemic H1N1 virus during therapy in 2 immunocompromised hosts. Clin Infect Dis. 2010 May 1; 50(9):1252-5. PubMed PMID: 20345239; PubMed Central PMCID: PMC2946636.

Memoli MJ, Hrabal RJ, Hassantoufighi A, Jagger BW, Sheng ZM, Eichelberger MC, Taubenberger JK. Rapid selection of a transmissible multidrug-resistant influenza A/H3N2 virus in an immunocompromised host. J Infect Dis. 2010 May 1; 201(9):1397-403. PubMed

PMID: 20350163; PubMed Central PMCID: PMC2851491.

Kash JC, Qi L, Dugan VG, Jagger BW, Hrabal RJ, Memoli MJ, Morens DM, Taubenberger JK. Prior infection with classical swine H1N1 influenza viruses is associated with protective immunity to the 2009 pandemic H1N1 virus. Influenza Other Respi Viruses. 2010 May 1; 4(3):121-7. PubMed PMID: 20409208; PubMed Central PMCID: PMC2859467.

Wang R, Taubenberger JK. Methods for molecular surveillance of influenza. Expert Rev Anti Infect Ther. 2010 May; 8(5):517-27. Review. PubMed PMID: 20455681; PubMed Central PMCID: PMC2882197.

Taubenberger JK, Kash JC. Influenza virus evolution, host adaptation, and pandemic formation. Cell Host Microbe. 2010 Jun 25; 7(6):440-51. Review. PubMed PMID: 20542248; PubMed Central PMCID: PMC2892379.

Taubenberger JK, Morens DM. Influenza: the once and future pandemic. Public Health Rep. 2010 Apr; 125 Suppl 3:16-26. Review. PubMed PMID: 20568566; PubMed Central PMCID: PMC2862331.

Jagger BW, Memoli MJ, Sheng ZM, Qi L, Hrabal RJ, Allen GL, Dugan VG, Wang R, Digard P, Kash JC, Taubenberger JK. The PB2-E627K mutation attenuates viruses containing the 2009 H1N1 influenza pandemic polymerase. MBio. 2010 May 18; 1(1). pii: e00067-10. PubMed PMID: 20689744; PubMed Central PMCID: PMC2912665.

Mollura DJ, Morens DM, Taubenberger JK, Bray M. The role of radiology in influenza: novel H1N1 and lessons learned from the 1918 pandemic. J Am Coll Radiol. 2010 Sep;7(9):690-7. PubMed PMID: 20816630.

Morens DM, Taubenberger JK, Fauci AS. The 2009 H1N1 Pandemic Influenza Virus: What Next? MBio. 2010 Sep 28; 1(4). pii: e00211-10. PubMed PMID: 20877580; PubMed Central PMCID: PMC2945198.

Morens DM, Taubenberger JK. Historical thoughts on influenza viral ecosystems,or behold a pale horse, dead dogs, failing fowl, and sick swine. Influenza Other Respi Viruses. 2010 Nov; 4(6):327-37. doi: 10.1111/j.1750-2659.2010.00148.x. Review. PubMed PMID: 20958926.

Morens DM, Taubenberger JK. An avian outbreak associated with panzootic equine influenza in 1872: an early example of highly pathogenic avian influenza? Influenza Other Respi Viruses. 2010 Nov; 4(6):373-7. doi: 10.1111/j.1750-2659.2010.00181.x. PubMed PMID: 20958931.

Morens DM, Taubenberger JK, Folkers GK, Fauci AS. Pandemic influenza's 500th anniversary. Clin Infect Dis. 2010 Dec 15; 51(12):1442-4. Epub 2010 Nov 10. PubMed

PMID: 21067353.

Safronetz D, Rockx B, Feldmann F, Belisle SE, Palermo RE, Brining D, Gardner D, Proll SC, Marzi A, Tsuda Y, Lacasse RA, Kercher L, York A, Korth MJ, Long D, Rosenke R, Shupert WL, Aranda CA, Mattoon JS, Kobasa D, Kobinger G, Li Y, Taubenberger JK, Richt JA, Parnell M, Ebihara H, Kawaoka Y, Katze MG, Feldmann H. Pandemic swine-origin H1N1 influenza A virus isolates show heterogeneous virulence in macaques. J Virol. 2011 Feb; 85(3):1214-23. Epub 2010 Nov 17. PubMed PMID: 21084481; PubMed Central PMCID: PMC3020514.

Sheng ZM, Chertow DS, Morens DM, Taubenberger JK. Fatal 1918 pneumonia case complicated by erythrocyte sickling. Emerg Infect Dis. 2010 Dec;16(12):2000-1. PubMed PMID: 21122243.

Morens DM, North M, Taubenberger JK. Eyewitness accounts of the 1510 influenza pandemic in Europe. Lancet. 2010 Dec 4; 376(9756):1894-5. PubMed PMID: 21155080.

Memoli MJ, Davis AS, Proudfoot K, Chertow DS, Hrabal RJ, Bristol T, Taubenberger JK. Multidrug-resistant 2009 pandemic influenza A(H1N1) viruses maintain fitness and transmissibility in ferrets. J Infect Dis. 2011 Feb 1; 203(3):348-57. Epub 2010 Dec 20. PubMed PMID: 21208927.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:

At the C.W. Bill Young Center, the Laboratory of Infectious Diseases (LID) focuses on viral vaccine development, host immune response to viruses, and viral molecular biology and genetics. Newer programs focus on developing vaccines, from basic research to clinical trials.

The Laboratory of Bacterial Diseases (LBD) focuses on the development of diagnostics, vaccines, and therapeutics for biodefense. Specifc research concerns the identification and analysis of bacterial virulence factors and their genetic regulation; structure-function analysis of bacterial proteins and other factors; disease pathogenesis.

The Laboratory of Viral Diseases (LVD) studies the basic mechanisms of viral entry into cells, regulation of viral gene expression, viral DNA replication, assembly and transport of viral proteins and particles, viral virulence, and humoral and cellular immunity, for DNA and RNA viruses. Applied research includes development of recombinant expression vectors, candidate vaccines, and antiviral agents.

[*] Including viruses and prions.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category A and B Priority Pathogens
- **USDA Select Agents and Toxins**
- **Other pathogens or toxins**
  Including non-Select Agent, NIAID Category A, B and C Priority Pathogens

Some Select Agent Toxin(s) below the *de minimus* level and thus exempt from registration with the Select Agent Program.

III. Outdoor Studies:
None

Form A, Part 2 (iii)

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

NIH, Dale and Betty Bumpers Vaccine Research Center

2. Where is it located (provide both address and geographical location)?

National Institutes of Health (NIH)
US Department of Health and Human Services
9000 Rockville Pike
Bethesda, Maryland 20892

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	89
BL3 (sqM)	0
BL4 (sqM)	0
Total (sqM)	89

4. The organizational structure of each facility.

I Total Number of Personnel 7

II Division of Personnel:

Military	0
Civilian	7

III Division of Personnel by Category:

Scientists	7
Engineers	0
Technicians	0
Administrative/Support	0

IV List the scientific disciplines represented in the scientific/engineering support staff.

Biochemistry
Biology
Immunology
Infectious Disease

Microbiology
Molecular Biology
Virology

V Are contractor staff working in the facility? If so, provide an approximate number.

No

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Health and Human Services (HHS)

VII What are the funding levels for the following program areas:

Research	$782,000
Development	$ 0
Test and evaluation	$ 0
Total	$782,000

VIII Briefly describe the publication policy of the facility:

All researchers are encouraged to publish results in peer-reviewed open literature. The NIH Public Access Policy (http://publicaccess.nih.gov/policy.htm) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National Library of Medicine's digital archive PubMed Central upon acceptance for publication. To help advance science and improve human health, the policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Geisbert TW, Bailey M, Geisbert JB, Asiedu C, Roederer M, Grazia-Pau M, Custers J, Jahrling P, Goudsmit J, Koup R, Sullivan NJ. Vector choice determines immunogenicity and potency of genetic vaccines against Angola Marburg virus in nonhuman primates. J Virol. 2010 Oct; 84(19):10386-94. Epub 2010 Jul 21. PubMed PMID: 20660192; PubMed Central PMCID: PMC2937810.

Hensley LE, Mulangu S, Asiedu C, Johnson J, Honko AN, Stanley D, Fabozzi G, Nichol ST, Ksiazek TG, Rollin PE, Wahl-Jensen V, Bailey M, Jahrling PB, Roederer M, Koup RA, Sullivan NJ. Demonstration of cross-protective vaccine immunity against an emerging pathogenic Ebolavirus Species. PLoS Pathog. 2010 May 20; 6(5):e1000904. PubMed PMID:

20502688; PubMed Central PMCID: PMC2873919.

Shedlock DJ, Bailey MA, Popernack PM, Cunningham JM, Burton DR, Sullivan NJ. Antibody-mediated neutralization of Ebola virus can occur by two distinct mechanisms. Virology. 2010 Jun 5; 401(2):228-35. Epub 2010 Mar 20. PubMed PMID: 20304456.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms* and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
The research focus of the Biodefense Research Laboratory, Vaccine Research Center (VRC) comprises three areas:

1. Development of vaccines and antivirals
2. Studies of the mechanism of vaccine-induced immune protection
3. Basic research to understand the mechanism of virus replication (entry) and neutralization

II. Agents Microorganisms and/or Toxins:

• **Other pathogens or toxins**

III. Outdoor Studies:
None

* Including viruses and prions.

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

NIH, Integrated Research Facility (IRF) - Rocky Mountain Laboratories (RML)

2. Where is it located (provide both address and geographical location)?

903 South 4th St.
Hamilton, Montana 59840

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	1361
BL3 (sqM)	56
BL4 (sqM)	631
Total (sqM)	2048

4. The organizational structure of each facility.

I Total Number of Personnel 99

II Division of Personnel:

Military	0
Civilian	99

III Division of Personnel by Category:

Scientists	70
Engineers	0
Technicians	29
Administrative/Support	0

IV List the scientific disciplines represented in the scientific/engineering support staff.

Bacteriology
Biology
Chemistry
Medicine
Prionology
Rickettsiology

Virology

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 5

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Health and Human Services (HHS)

VII What are the funding levels for the following program areas:

Research	$25,980,983
Development	$ 0
Test and evaluation	$ 0
Total	$25,980,983

VIII Briefly describe the publication policy of the facility:

All researchers are encouraged to publish results in peer-reviewed open literature.

The NIH Public Access Policy (http://publicaccess.nih.gov/policy.htm) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National Library of Medicine's digital archive PubMed Central upon acceptance for publication. To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Speare JO, Offerdahl DK, Hasenkrug A, Carmody AB, Baron GS. GPI anchoring facilitates propagation and spread of misfolded Sup35 aggregates in mammalian cells. EMBO J. 2010 Feb 17; 29(4):782-94. Epub 2010 Jan 7. PubMed PMID: 20057357; PubMed Central PMCID: PMC2829165.

Valmas C, Grosch MN, Schümann M, Olejnik J, Martinez O, Best SM, Krähling V,Basler CF, Mühlberger E. Marburg virus evades interferon responses by a mechanism distinct from ebola virus. PLoS Pathog. 2010 Jan 15; 6(1):e1000721. PubMed PMID: 20084112; PubMed Central PMCID: PMC2799553.

Laurent-Rolle M, Boer EF, Lubick KJ, Wolfinbarger JB, Carmody AB, Rockx B, Liu W,

Ashour J, Shupert WL, Holbrook MR, Barrett AD, Mason PW, Bloom ME, Garc García-Sastre A, Khromykh AA, Best SM. The NS5 protein of the virulent West Nile virus NY99 strain is a potent antagonist of type I interferon-mediated JAK-STAT signaling. J Virol. 2010 Apr; 84(7):3503-15. Epub 2010 Jan 27. PubMed PMID: 20106931; PubMed Central PMCID: PMC2838099.

Levine JR, Prescott J, Brown KS, Best SM, Ebihara H, Feldmann H. Antagonism of type I interferon responses by new world hantaviruses. J Virol. 2010 Nov; 84(22):11790-801. Epub 2010 Sep 15. PubMed PMID: 20844031; PubMed Central PMCID: PMC2977899.

Risi GF, Bloom ME, Hoe NP, Arminio T, Carlson P, Powers T, Feldmann H, Wilson D. Preparing a community hospital to manage work-related exposures to infectious agents in BioSafety level 3 and 4 laboratories. Emerg Infect Dis. 2010 Mar; 16(3):373-8. PubMed PMID: 20202409.

Engel AR, Mitzel DN, Hanson CT, Wolfinbarger JB, Bloom ME, Pletnev AG. Chimeric Tick-Borne Encephalitis/Dengue Virus Is Attenuated in Ixodes scapularis Ticks and Aedes aegypti Mosquitoes. Vector Borne Zoonotic Dis. 2010 Dec 13. [Epub ahead of print] PubMed PMID: 21142950.

Ireland R, Olivares-Zavaleta N, Warawa JM, Gherardini FC, Jarrett C, Hinnebusch BJ, Belisle JT, Fairman J, Bosio CM. Effective, broad spectrum control of virulent bacterial infections using cationic DNA liposome complexes combined with bacterial antigens. PLoS Pathog. 2010 May 27; 6(5):e1000921. PubMed PMID: 20523903; PubMed Central PMCID: PMC2877747.

Jones A, Bosio C, Duffy A, Goodyear A, Schriefer M, Dow S. Protection against pneumonic plague following oral immunization with a non-replicating vaccine. Vaccine. 2010 Aug 16; 28(36):5924-9. Epub 2010 Jun 19. PubMed PMID: 20600517.

Anderson RV, Crane DD, Bosio CM. Long lived protection against pneumonic tularemia is correlated with cellular immunity in peripheral, not pulmonary, organs. Vaccine. 2010 Sep 14; 28(40):6562-72. Epub 2010 Aug 3. PubMed PMID: 20688042; PubMed Central PMCID: PMC2939155.

Kim JI, Cali I, Surewicz K, Kong Q, Raymond GJ, Atarashi R, Race B, Qing L, Gambetti P, Caughey B, Surewicz WK. Mammalian prions generated from bacterially expressed prion protein in the absence of any mammalian cofactors. J Biol Chem. 2010 May 7; 285(19):14083-7. Epub 2010 Mar 19. PubMed PMID: 20304915; PubMed Central PMCID: PMC2863186.

Bessen RA, Shearin H, Martinka S, Boharski R, Lowe D, Wilham JM, Caughey B, Wiley JA. Prion shedding from olfactory neurons into nasal secretions. PLoS Pathog. 2010 Apr 15; 6(4):e1000837. PubMed PMID: 20419120; PubMed Central PMCID: PMC2855443.

Wilham JM, Orrú CD, Bessen RA, Atarashi R, Sano K, Race B, Meade-White KD, Taubner LM, Timmes A, Caughey B. Rapid end-point quantitation of prion seeding activity with sensitivity comparable to bioassays. PLoS Pathog. 2010 Dec 2;6(12):e1001217. PubMed PMID: 21152012; PubMed Central PMCID: PMC2996325.

Sturdevant DE, Virtaneva K, Martens C, Bozinov D, Ogundare O, Castro N, Kanakabandi K, Beare PA, Omsland A, Carlson JH, Kennedy AD, Heinzen RA, Celli J, Greenberg DE, DeLeo FR, Porcella SF. Host-microbe interaction systems biology: lifecycle transcriptomics and comparative genomics. Future Microbiol. 2010 Feb; 5(2):205-19. Review. Erratum in: Future Microbiol. 2010 Mar; 5(3):526. Ohmsland, Anders [corrected to Omsland, Anders]. PubMed PMID: 20143945; PubMed Central PMCID: PMC2846718.

Johansson A, Celli J, Conlan W, Elkins KL, Forsman M, Keim PS, Larsson P, Manoil C, Nano FE, Petersen JM, Sjöstedt A. Objections to the transfer of Francisella novicida to the subspecies rank of Francisella tularensis. Int J Syst Evol Microbiol. 2010 Aug; 60(Pt 8):1717-8; author reply 1718-20. PubMed PMID: 20688748.

Knodler LA, Vallance BA, Celli J, Winfree S, Hansen B, Montero M, Steele-Mortimer O. Dissemination of invasive Salmonella via bacterial-induced extrusion of mucosal epithelia. Proc Natl Acad Sci U S A. 2010 Oct 12; 107(41):17733-8. Epub 2010 Sep 27. PubMed PMID: 20876119; PubMed Central PMCID: PMC2955089.

Chesebro B, Race B, Meade-White K, Lacasse R, Race R, Klingeborn M, Striebel J, Dorward D, McGovern G, Jeffrey M. Fatal transmissible amyloid encephalopathy: a new type of prion disease associated with lack of prion protein membrane anchoring. PLoS Pathog. 2010 Mar 5; 6(3):e1000800. PubMed PMID: 20221436; PubMed Central PMCID: PMC2832701.

Belay ED, Schonberger LB, Brown P, Priola SA, Chesebro B, Will RG, Asher DM. Disinfection and sterilization of prion-contaminated medical instruments. Infect Control Hosp Epidemiol. 2010 Dec; 31(12):1304-6; author reply 1306-8. PubMed PMID: 21047181.

Klingeborn M, Race B, Meade-White KD, Rosenke R, Striebel JF, Chesebro B. Crucial role for prion protein membrane anchoring in the neuroinvasion and neural spread of prion infection. J Virol. 2011 Feb; 85(4):1484-94. Epub 2010 Dec 1. PubMed PMID: 21123371.

Graves SF, Kobayashi SD, DeLeo FR. Community-associated methicillin-resistant Staphylococcus aureus immune evasion and virulence. J Mol Med. 2010 Feb; 88(2):109-14. Epub 2010 Jan 5. Review. PubMed PMID: 20049412; PubMed Central PMCID: PMC2852573.

DeLeo FR, Musser JM. Axis of coinfection evil. J Infect Dis. 2010 Feb 15; 201(4):488-90. PubMed PMID: 20078214.

Olsen RJ, Sitkiewicz I, Ayeras AA, Gonulal VE, Cantu C, Beres SB, Green NM, Lei B,

Humbird T, Greaver J, Chang E, Ragasa WP, Montgomery CA, Cartwright J Jr, McGeer A, Low DE, Whitney AR, Cagle PT, Blasdel TL, DeLeo FR, Musser JM. Decreased necrotizing fasciitis capacity caused by a single nucleotide mutation that alters a multiple gene virulence axis. Proc Natl Acad Sci U S A. 2010 Jan 12; 107(2):888-93. Epub 2010 Jan 4. PubMed PMID: 20080771; PubMed Central PMCID: PMC2818956.

Olsen RJ, Kobayashi SD, Ayeras AA, Ashraf M, Graves SF, Ragasa W, Humbird T, Greaver JL, Cantu C, Swain JL, Jenkins L, Blasdel T, Cagle PT, Gardner DJ, DeLeo FR, Musser JM. Lack of a major role of Staphylococcus aureus Panton-Valentine leukocidin in lower respiratory tract infection in nonhuman primates. Am J Pathol. 2010 Mar; 176(3):1346-54. Epub 2010 Jan 21. PubMed PMID: 20093487; PubMed Central PMCID: PMC2832154.

Graves SF, Kobayashi SD, Braughton KR, Diep BA, Chambers HF, Otto M, Deleo FR. Relative contribution of Panton-Valentine leukocidin to PMN plasma membrane permeability and lysis caused by USA300 and USA400 culture supernatants. Microbes Infect. 2010 Jun; 12(6):446-56. Epub 2010 Feb 19. PubMed PMID: 20172045; PubMed Central PMCID: PMC2883622.

Shea PR, Virtaneva K, Kupko JJ 3rd, Porcella SF, Barry WT, Wright FA, Kobayashi SD, Carmody A, Ireland RM, Sturdevant DE, Ricklefs SM, Babar I, Johnson CA, Graham MR, Gardner DJ, Bailey JR, Parnell MJ, Deleo FR, Musser JM. Interactome analysis of longitudinal pharyngeal infection of cynomolgus macaques by group A Streptococcus. Proc Natl Acad Sci U S A. 2010 Mar 9; 107(10):4693-8. Epub 2010 Feb 23. PubMed PMID: 20179180; PubMed Central PMCID: PMC2842040.

Deleo FR, Otto M, Kreiswirth BN, Chambers HF. Community-associated methicillin-resistant Staphylococcus aureus. Lancet. 2010 May 1; 375(9725):1557-68. Epub 2010 Mar 5. Review. PubMed PMID: 20206987.

Diep BA, Chan L, Tattevin P, Kajikawa O, Martin TR, Basuino L, Mai TT, Marbach H, Braughton KR, Whitney AR, Gardner DJ, Fan X, Tseng CW, Liu GY, Badiou C, Etienne J, Lina G, Matthay MA, DeLeo FR, Chambers HF. Polymorphonuclear leukocytes mediate Staphylococcus aureus Panton-Valentine leukocidin-induced lung inflammation and injury. Proc Natl Acad Sci U S A. 2010 Mar 23; 107(12):5587-92. Epub 2010 Mar 15. PubMed PMID: 20231457; PubMed Central PMCID: PMC2851770.

Kobayashi SD, Braughton KR, Palazzolo-Ballance AM, Kennedy AD, Sampaio E, Kristosturyan E, Whitney AR, Sturdevant DE, Dorward DW, Holland SM, Kreiswirth BN, Musser JM, DeLeo FR. Rapid neutrophil destruction following phagocytosis of Staphylococcus aureus. J Innate Immun. 2010; 2(6):560-75. Epub 2010 Jun 26. PubMed PMID: 20587998.

Ventura CL, Malachowa N, Hammer CH, Nardone GA, Robinson MA, Kobayashi SD, DeLeo FR. Identification of a novel Staphylococcus aureus two-component leukotoxin using

cell surface proteomics. PLoS One. 2010 Jul 16; 5(7):e11634. PubMed PMID: 20661294; PubMed Central PMCID: PMC2905442.

Malachowa N, DeLeo FR. Mobile genetic elements of Staphylococcus aureus. Cell Mol Life Sci. 2010 Sep; 67(18):3057-71. Epub 2010 Jul 29. Review. PubMed PMID: 20668911; PubMed Central PMCID: PMC2929429.

Kennedy AD, Bubeck Wardenburg J, Gardner DJ, Long D, Whitney AR, Braughton KR, Schneewind O, DeLeo FR. Targeting of alpha-hemolysin by active or passive immunization decreases severity of USA300 skin infection in a mouse model. J Infect Dis. 2010 Oct 1; 202(7):1050-8. PubMed PMID: 20726702; PubMed Central PMCID: PMC2945289.

Kennedy AD, Porcella SF, Martens C, Whitney AR, Braughton KR, Chen L, Craig CT, Tenover FC, Kreiswirth BN, Musser JM, DeLeo FR. Complete nucleotide sequence analysis of plasmids in strains of Staphylococcus aureus clone USA300 reveals a high level of identity among isolates with closely related core genome sequences. J Clin Microbiol. 2010 Dec; 48(12):4504-11. Epub 2010 Oct 13. PubMed PMID: 20943864; PubMed Central PMCID: PMC3008496.

Cheung GY, Rigby K, Wang R, Queck SY, Braughton KR, Whitney AR, Teintze M, DeLeo FR, Otto M. Staphylococcus epidermidis strategies to avoid killing by human neutrophils. PLoS Pathog. 2010 Oct 7; 6(10). pii: e1001133. PubMed PMID: 20949069; PubMed Central PMCID: PMC2951371.

Li M, Cheung GY, Hu J, Wang D, Joo HS, Deleo FR, Otto M. Comparative analysis of virulence and toxin expression of global community-associated methicillin-resistant Staphylococcus aureus strains. J Infect Dis. 2010 Dec 15; 202(12):1866-76. Epub 2010 Nov 4. PubMed PMID: 21050125.

Schwartz JA, Buonocore L, Suguitan AL Jr, Silaghi A, Kobasa D, Kobinger G, Feldmann H, Subbarao K, Rose JK. Potent vesicular stomatitis virus-based avian influenza vaccines provide long-term sterilizing immunity against heterologous challenge. J Virol. 2010 May; 84(9):4611-8. Epub 2010 Feb 24. PubMed PMID: 20181720; PubMed Central PMCID: PMC2863739.

York J, Berry JD, Ströher U, Li Q, Feldmann H, Lu M, Trahey M, Nunberg JH. An antibody directed against the fusion peptide of Junin virus envelope glycoprotein GPC inhibits pH-induced membrane fusion. J Virol. 2010 Jun; 84(12):6119-29. Epub 2010 Apr 14. PubMed PMID: 20392854; PubMed Central PMCID: PMC2876654.

Prescott J, Hall P, Acuna-Retamar M, Ye C, Wathelet MG, Ebihara H, Feldmann H, Hjelle B. New World hantaviruses activate IFNlambda production in type I IFN-deficient vero E6 cells. PLoS One. 2010 Jun 17; 5(6):e11159. PubMed PMID: 20567522; PubMed Central PMCID: PMC2887373.

Geisbert TW, Hensley LE, Geisbert JB, Leung A, Johnson JC, Grolla A, Feldmann H. Postexposure treatment of Marburg virus infection. Emerg Infect Dis. 2010 Jul; 16(7):1119-22. PubMed PMID: 20587184.

Safronetz D, Lopez JE, Sogoba N, Traore' SF, Raffel SJ, Fischer ER, Ebihara H, Branco L, Garry RF, Schwan TG, Feldmann H. Detection of Lassa virus, Mali. Emerg Infect Dis. 2010 Jul; 16(7):1123-6. PubMed PMID: 20587185.

Rockx B, Bossart KN, Feldmann F, Geisbert JB, Hickey AC, Brining D, Callison J, Safronetz D, Marzi A, Kercher L, Long D, Broder CC, Feldmann H, Geisbert TW. A novel model of lethal Hendra virus infection in African green monkeys and the effectiveness of ribavirin treatment. J Virol. 2010 Oct; 84(19):9831-9. Epub 2010 Jul 21. PubMed PMID: 20660198; PubMed Central PMCID: PMC2937751.

Nakayama E, Yokoyama A, Miyamoto H, Igarashi M, Kishida N, Matsuno K, Marzi A, Feldmann H, Ito K, Saijo M, Takada A. Enzyme-linked immunosorbent assay for detection of filovirus species-specific antibodies. Clin Vaccine Immunol. 2010 Nov; 17(11):1723-8. Epub 2010 Sep 22. PubMed PMID: 20861331; PubMed Central PMCID: PMC2976089.

Porotto M, Rockx B, Yokoyama CC, Talekar A, Devito I, Palermo LM, Liu J, Cortese R, Lu M, Feldmann H, Pessi A, Moscona A. Inhibition of Nipah virus infection in vivo: targeting an early stage of paramyxovirus fusion activation during viral entry. PLoS Pathog. 2010 Oct 28;6(10):e1001168. PubMed PMID: 21060819; PubMed Central PMCID: PMC2965769.

Safronetz D, Rockx B, Feldmann F, Belisle SE, Palermo RE, Brining D, Gardner D, Proll SC, Marzi A, Tsuda Y, Lacasse RA, Kercher L, York A, Korth MJ, Long D, Rosenke R, Shupert WL, Aranda CA, Mattoon JS, Kobasa D, Kobinger G, Li Y, Taubenberger JK, Richt JA, Parnell M, Ebihara H, Kawaoka Y, Katze MG, Feldmann H. Pandemic swine-origin H1N1 influenza A virus isolates show heterogeneous virulence in macaques. J Virol. 2011 Feb;85(3):1214-23. Epub 2010 Nov 17. PubMed PMID: 21084481; PubMed Central PMCID: PMC3020514.

Ogawa H, Miyamoto H, Ebihara H, Ito K, Morikawa S, Feldmann H, Takada A. Detection of all known filovirus species by reverse transcription-polymerase chain reaction using a primer set specific for the viral nucleoprotein gene. J Virol Methods. 2011 Jan;171(1):310-3. Epub 2010 Nov 17. PubMed PMID: 21093485.

Brett PJ, Burtnick MN, Heiss C, Azadi P, DeShazer D, Woods DE, Gherardini FC. Burkholderia thailandensis oacA mutants facilitate the expression of Burkholderia mallei-like O polysaccharides. Infect Immun. 2011 Feb; 79(2):961-9. Epub 2010 Nov 29. PubMed PMID: 21115721.

Kleba B, Clark TR, Lutter EI, Ellison DW, Hackstadt T. Disruption of the Rickettsia rickettsii Sca2 autotransporter inhibits actin-based motility. Infect Immun. 2010 May; 78(5):2240-7. Epub 2010 Mar 1. PubMed PMID: 20194597; PubMed Central PMCID:

PMC2863521.

Mital J, Miller NJ, Fischer ER, Hackstadt T. Specific chlamydial inclusion membrane proteins associate with active Src family kinases in microdomains that interact with the host microtubule network. Cell Microbiol. 2010 Sep 1; 12(9):1235-49. Epub 2010 Mar 19. PubMed PMID: 20331642; PubMed Central PMCID: PMC2923664.

Lutter EI, Bonner C, Holland MJ, Suchland RJ, Stamm WE, Jewett TJ, McClarty G, Hackstadt T. Phylogenetic analysis of Chlamydia trachomatis Tarp and correlation with clinical phenotype. Infect Immun. 2010 Sep; 78(9):3678-88. Epub 2010 Jul 6. PubMed PMID: 20605986; PubMed Central PMCID: PMC2937449.

Jewett TJ, Miller NJ, Dooley CA, Hackstadt T. The conserved Tarp actin binding domain is important for chlamydial invasion. PLoS Pathog. 2010 Jul 15; 6(7):e1000997. PubMed PMID: 20657821; PubMed Central PMCID: PMC2904776.

Moore L, Mead D, Dooley C, Sager J, Hackstadt T. The trans-Golgi SNARE syntaxin 6 is recruited to the chlamydial inclusion membrane. Microbiology. 2010 Nov 25. [Epub ahead of print] PubMed PMID: 21109560.

Sutten EL, Norimine J, Beare PA, Heinzen RA, Lopez JE, Morse K, Brayton KA, Gillespie JJ, Brown WC. Anaplasma marginale type IV secretion system proteins VirB2, VirB7, VirB11, and VirD4 are immunogenic components of a protective bacterial membrane vaccine. Infect Immun. 2010 Mar;78(3):1314-25. Epub 2010 Jan 11. PubMed PMID: 20065028; PubMed Central PMCID: PMC2825951.

Howe D, Shannon JG, Winfree S, Dorward DW, Heinzen RA. Coxiella burnetii phase I and II variants replicate with similar kinetics in degradative phagolysosome-like compartments of human macrophages. Infect Immun. 2010 Aug; 78(8):3465-74. Epub 2010 Jun 1. PubMed PMID: 20515926; PubMed Central PMCID: PMC2916283.

Huang B, Troese MJ, Howe D, Ye S, Sims JT, Heinzen RA, Borjesson DL, Carlyon JA. Anaplasma phagocytophilum APH_0032 is expressed late during infection and localizes to the pathogen-occupied vacuolar membrane. Microb Pathog. 2010 Nov; 49(5):273-84. Epub 2010 Jun 30. PubMed PMID: 20600793; PubMed Central PMCID: PMC2919654.

Gilk SD, Beare PA, Heinzen RA. Coxiella burnetii expresses a functional Δ24 sterol reductase. J Bacteriol. 2010 Dec; 192(23):6154-9. Epub 2010 Sep 24. PubMed PMID: 20870767; PubMed Central PMCID: PMC2981196.

Vadyvaloo V, Jarrett C, Sturdevant DE, Sebbane F, Hinnebusch BJ. Transit through the flea vector induces a pretransmission innate immunity resistance phenotype in Yersinia pestis. PLoS Pathog. 2010 Feb 26; 6(2):e1000783. PubMed PMID: 20195507; PubMed Central PMCID: PMC2829055.

Derbise A, Chenal-Francisque V, Huon C, Fayolle C, Demeure CE, Chane-Woon-Ming B, Médigue C, Hinnebusch BJ, Carniel E. Delineation and analysis of chromosomal regions specifying Yersinia pestis. Infect Immun. 2010 Sep; 78(9):3930-41. Epub 2010 Jul 6. PubMed PMID: 20605981; PubMed Central PMCID: PMC2937459.

Comer JE, Sturdevant DE, Carmody AB, Virtaneva K, Gardner D, Long D, Rosenke R, Porcella SF, Hinnebusch BJ. Transcriptomic and innate immune responses to Yersinia pestis in the lymph node during bubonic plague. Infect Immun. 2010 Dec;78(12):5086-98. Epub 2010 Sep 27. PubMed PMID: 20876291; PubMed Central PMCID: PMC2981309.

Sebbane F, Jarrett C, Gardner D, Long D, Hinnebusch BJ. Role of the Yersinia pestis yersiniabactin iron acquisition system in the incidence of flea-borne plague. PLoS One. 2010 Dec 17; 5(12):e14379. PubMed PMID: 21179420; PubMed Central PMCID: PMC3003698.

Moore RA, Timmes A, Wilmarth PA, Priola SA. Comparative profiling of highly enriched 22L and Chandler mouse scrapie prion protein preparations. Proteomics. 2010 Aug; 10(15):2858-69. PubMed PMID: 20518029.

Steele-Mortimer O. Exploitation of the ubiquitin system by invading bacteria. Traffic. 2011 Feb; 12(2):162-9. doi: 10.1111/j.1600-0854.2010.01137.x. Epub 2010 Nov 24. PubMed PMID: 20977569; PubMed Central PMCID: PMC3038682.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:

NIH RML scientists broadly study pathogens that cause viral hemorrhagic fevers, viral encephalitis, and certain respiratory diseases. This work employs investigations in cell culture; animal models, including nonhuman primates; reservoir species; and arthropod hosts in order to elucidate the viral pathogenesis, immune responses, molecular evolution, cellular and molecular biology, and vector-host interactions. Specifically, studies include pathogenesis and pathophysiology of high-containment pathogens using molecular technologies; immune responses to infection and vaccination of viral pathogens; vector/reservoir transmission of viral pathogens and development of new vaccine candidates; in vitro and *in vivo* systems to study the interactions between viral pathogens or viral components and host cells; and epidemiology and ecology of pathogens.

Research activities address pathogenesis studies, vaccinology, and development of therapeutic countermeasures and rapid diagnostic assays in support of the civilian biodefense program.

[*] Including viruses and prions.

II. Agents Microorganisms and/or Toxins:

- **HHS Select Agents and Toxins**
  Including NIAID Category A, B and C Priority Pathogens
- **Overlap Select Agents**
  Including NIAID Category A, B and C Priority Pathogens
- **USDA Select Agents and Toxins**
- **Other pathogens or toxins**
  Including non-Select Agent, NIAID Category A, B and C Priority Pathogens

III. Outdoor Studies:
None

Form A, Part 2 (iii)

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Foreign Disease-Weed Science Research Unit

2. Where is it located (provide both address and geographical location)?

1301 Ditto Avenue
Fort Detrick, Maryland 21702

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	105
BL3 (sqM)	950
BL4 (sqM)	0
Total (sqM)	1055

BL-2 laboratories; enhanced by HEPA air filtration. BL3 plant pathogen containment facility with HEPA air filtration, steam sterilization of wastewater and personnel shower-out procedures.

4. The organizational structure of each facility.

I Total Number of Personnel 43

II Division of Personnel:

Military	0
Civilian	43

III Division of Personnel by Category:

Scientists	12
Engineers	0
Technicians	24
Administrative/Support	7

IV List the scientific disciplines represented in the scientific/engineering support staff.

Agronomy
Biological Control

Horticulture
Plant Biochemistry
Plant Molecular Biology
Plant Pathology
Plant Physiology
Plant Virology
Weed Science

V Are contractor staff working in the facility? If so, provide an approximate number.

No

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Agriculture (USDA)

VII What are the funding levels for the following program areas:

Research	$5,600,000
Development	$ 0
Test and evaluation	$ 0
Total	$5,600,000

VIII Briefly describe the publication policy of the facility:

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and publish in books and proceedings. No classified research is conducted at this facility.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Berner, D.K. 2010. BLUP, a new paradigm in host-range determination. Biological Control. 53:143-152.

Damsteegt, V.D., Postnikova, E.N., Stone, A.L., Kuhlmann, M., Wilson, C., Sechler, A.J., Schaad, N.W., Brlansky, R.H., Schneider, W.L. 2010. The relevance of Murraya paniculata and related species as potential hosts and inoculum reservoirs of Candidatus Liberibacter asiaticus, causal agent of Huanglongbing (HLB). Plant Disease. 94:528-533.

Erper, I., Tunali, B., Berner, D.K. 2010. First report of leaf spot on horseweed (Conyza canadensis L.) caused by Septoria erigerontis in Turkey. Plant Disease. 94:918.

Luster, D.G., Mcmahon, M.B., Carter, M.L., Fortis, L.L., Nunez, A. Proteomic analysis of germinating urediniospores of Phakopsora pachyrhizi, causal agent of Asian Soybean Rust. Proteomics. 2010, 3549-3557.

Mejri, D., Berner, D.K., Souissi, T. 2010. Evaluation of Puccinia carduorum for biological control of Carduus pycnocephalus in Tunisia. Biocontrol Science and Technology. Vol. 20, No. 8, 2010, 787-790.

Mejri, D., Souissi, T., Berner, D.K. 2010. Evaluation of Puccinia carduorum for biological control of Italian thistle (Carduus pycnocephalus). Biocontrol Science and Technology. 20:787-790.

Oh, C., Pedley, K.F., Martin, G.B. 2010. Tomato 14-3-3 protein 7 (TFT7) positively regulates immunity-associated programmed cell death by enhancing accumulation and signaling ability of MAPKKKalpha. The Plant Cell. 22(1):260-272.

Schaad, N.W., Schuenzel, E. 2010. Sensitive molecular diagnostic assays to mitigate the risks of asymptomatic bacterial diseases of plants. Critical Reviews in Immunology. 50(3):271-275.

Stone, C.L., Posada-Buitrago, M.L., Boore, J.L., Frederick, R.D. 2010. Analysis of the complete mitochondrial genome sequences of the soybean rust pathogens Phakopsora pachyrhizi and P. meibomiae. Mycologia. 102(4):887-987.

Tooley, P.W., Carras, M.M., Sechler, A.J., Rajasab, A.H. 2010. Real-time PCR detection of sorghum ergot pathogens Claviceps africana, C. sorghi, and C. sorghicola. Journal of Phytopathology. doi: 10.1111/j.1439-0434.2010.01683.

Widmer, T.L. 2010. Differentiating Phytophthora spp. isolated from leaves and stems of rhododendron plants. Plant Health Progress. doi: 10.1094/PHP-2010-0317-01-RS.

Widmer, T.L. 2010. Phytophthora kernoviae oospore maturity, germination, and infection. Fungal Biology. doi:10.1016/j.funbio.2010.06.001. 114:661-668.

Widmer, T.L. 2010. Whole plant inoculations of Viburnum species and cultivars testing for susceptibility to Phytophthora ramorum. Journal of Environmental Horticulture. 28:197-202.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

[*] Including viruses and prions.

I. Objectives:
The USDA, Agricultural Research Service, Foreign Disease-Weed Science Research Unit has two distinct missions united by a common relationship to plant pathology and the unit's unique BL-3 plant pathogen laboratory and greenhouse containment facilities.

The mission of the foreign disease program is to develop techniques for the rapid detection and identification of new and emerging crop pathogens, and to provide fundamental information on emerging pathogens for risk assessment and the development of practical phytosanitary regulations for the import and export of agricultural commodities and germplasm.

The mission of the weed biological control program is to collect foreign pathogens overseas from weeds in their native habitat, and to evaluate, characterize and release the pathogens in the U.S. for biological control of introduced weeds, leading to improved, sustainable weed control practices in agricultural systems with reduced dependence on chemical herbicides.

II. Agents Microorganisms and/or Toxins:

- **USDA PPQ Select Agents and Toxins**
- **Other pathogens or toxins**

The agents studied are foreign and/or emerging pathogens of plants that have an agricultural base. The agents studied include viruses, bacteria, and fungi. The majority of the agents studied are not classified by USDA as select agents. The agents classified as select agents are pathogens that pose a threat to our plant production systems, our agricultural economy, and exports.

III. Outdoor Studies:
None

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

National Animal Disease Center (NADC)

2. Where is it located (provide both address and geographical location)?

1920 Dayton Avenue
Ames, Iowa 50010

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	4410
BL3 (sqM)	2489
BL4 (sqM)	0
Total (sqM)	6899

BSL-3Ag Large Animal Space - enhancements include HEPA-filtered supply air; dual HEPA filtered exhaust; air-tight doors; shower-in /out of each animal room; Heat-treated waste; Steam-treated rendering for carcasses; stainless steel penning and gating systems; epoxy-coated floors, epoxy-covered surfaces.

4. The organizational structure of each facility.

I Total Number of Personnel 292

II Division of Personnel:

Military	0
Civilian	292

III Division of Personnel by Category:

Scientists	44
Engineers	0
Technicians	70
Administrative/Support	178

IV List the scientific disciplines represented in the scientific/engineering support staff.

Agricultural Engineering
Animal Science
Biochemistry
Bioinformatics
Biology
Biotechnology
Cell Biology
Clinical Immunology
Computational Biology
Ecology
Genetics
Genomics
Immunology
Infectious Disease
Mass Spectrometry
Mass Spectrometry Biochemistry
Microbiology
Molecular Biology
Pathogenesis
Pathology
Physiology
Prionology
Proteomics
Statistics
Structural Biology
Vaccine Evaluation
Veterinarian
Veterinary Clinical Research
Veterinary Medicine
Virology

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 13

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Agriculture (USDA)

VII What are the funding levels for the following program areas:

Research	$32,100,000
Development	$ 0
Test and evaluation	$ 0
Total	$32,100,000

VIII Briefly describe the publication policy of the facility:

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and publish in books and proceedings. No classified research is conducted at this facility.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Adhikary, R., Mukherjee, P., Krishnamoorthy, G., Kunkle, R.A., Casey, T.A., Rasmussen, M.A., Petrich, J.W. 2010. Fluorescence Spectroscopy of the Retina for Diagnosis of Transmissible Spongiform Encephalopathies. Analytical Chemistry. 82(10):4097-4101.

Bannantine, J.P., Stabel, J.R., Bayles, D.O., Geisbrecht, B. 2010. Characteristics of an Extensive Mycobacterium avium subspecies paratuberculosis Recombinant Protein Set. Protein Expression and Purification. 72(2):223-233.

Barnhill, A.E., Hecker, L.A., Kohutyuk, O., Buss, J.E., Honavar, V., West-Greenlee, H.M. 2010. Characterization of the Retinal Proteome During Rod Photoreceptor Genesis. BMC Research Notes 2010. 3:25. Available: http://www.biomedcentral.com/1756-0500/3/25.

Barnhill, A.E., Weeks, K.E., Xiong, N., Day, T.A., Carlson, S.A. 2010. Identification of Multiresistant Salmonella Capable of Subsisting on Antibiotics. Applied and Environmental Microbiology. 76(8):2678-2680.

Blanchard, P.C., Ridpath, J.F., Walker, J.B., Hietala, S.K. 2010. An Outbreak of Late-Term Abortions, Premature Births, and Congenital Deformities Associated with a Bovine Viral Diarrhea Virus 1 Subtype b that Induces Thrombocytopenia. Journal of Veterinary Diagnostic Investigation. 22(1):128-131.

Charles, R.C., Sheikh, A., Krastins, B., Harris, J., Bhuiyan, S.M., Larocque, R.C., Logvinenko, T., Sarracino, D.A., Kudva, I.T., Eisenstein, J., Podolsky, M.J., Kalsy, A., Ludwig, A., Manohar, J., Calderwood, S.B., Qadri, F., Ryan, E.T. 2010. Characterization of Anti-Salmonella enterica Serotype Typhi Antibody Responses in Bacteremic Bangladeshi Patients using Immuno-affinity Proteomic-based Technology (IPT). Clinical and Vaccine

Immunology. Available: http://cvi.asm.org/cgi/reprint/CVI.00104-10v1.pdf.

Cheung, A.K., Wu, G., Wang, D., Bayles, D.O., Lager, K.M., Vincent, A.L. 2010. Identification and Molecular Cloning of a Novel Porcine Parvovirus. Archives of Virology. 155(5):801-806.

Choi, C.J., Anantharam, V., Martin, D.P., Nicholson, E.M., Richt, J., Kanthasamy, A., Kanthasamy, A. 2010. Manganese Upregulates Cellular Prion Protein and Contributes to Altered Stabilization and Proteolysis: Relevance to Role of Metals in Pathogenesis of Prion Disease. Toxicological Sciences. 115(2):535-546.

Ciacci-Zanella, J.R., Vincent, A.L., Prickett, J.R., Zimmerman, S.M., Zimmerman, J.J. 2010. Detection of Anti-Influenza A Nucleoprotein Antibodies in Pigs Using a Commercial Influenza Epitope-Blocking Enzyme-Linked Immunosorbent Assay Developed for Avian Species. Journal of Veterinary Diagnostic Investigation. 22(1):3-9.

Davis, W.C., Park, K.T., Hamilton, M.J., Waters, W.R. 2010. Understanding the Mechanisms of Immunopathogenesis of Human and Bovine Tuberculosis. Journal of Zoonoses. 1(1):17-23.

Ellingson, J.S., Wang, Y., Layton, S., Ciacci-Zanella, J., Roof, M.B., Faaberg, K.S. 2010. Vaccine Efficacy of Porcine Reproductive and Respiratory Syndrome Virus Chimeras. Vaccine. 28(14):2679-2686.

Faaberg, K.S., Kehrli, Jr., M.E., Lager, K.M., Guo, B., Han, J. 2010. In vivo growth of porcine reproductive and respiratory syndrome virus engineered Nsp2 deletion mutants. Virus Research. 154(1-2):77-85.

Fach, S.J., Olivier, A., Gallup, J.M., Waters, T.E., Ackermann, M., Lehmkuhl, H.D., Sacco, R.E. 2010. Differential Expression of Cytokine Transcripts in Neonatal and Adult Ovine Alveolar Macrophages in Response to Respiratory Syncytial Virus or Toll-Like Receptor Ligation. Veterinary Immunology and Immunopathology. 136(1-2):55-64.

Fulton, R.M., Rimler, R.B. 2010. Epidemiologic Investigation of Riemerella anatipestifer in a Commercial Duck Company by Serotyping and DNA Fingerprinting. Avian Diseases. 54(2):969-972.

Graham, T.W., Breher, J.E., Farver, T.B., Cullor, J.S., Kehrli, Jr., M.E., Oberbauer, A.M. 2010. Biological Markers of Neonatal Calf Performance: the Relationship of Insulin-like Growth Factor-I, Zinc, and Copper to Poor Neonatal Growth. Journal of Animal Science. 88(8):2585-2593.

Gopaul, K.K., Sells, J., Bricker, B.J., Crasta, O.R., Whatmore, A.M. 2010. Rapid and Reliable Single Nucleotide Polymorphism-Based Differentiation of Brucella Live Vaccine

Strains from Field Strains. Journal of Clinical Microbiology. 48(4):1461-1464.

Hailat, N.Q., Hananeh, W.M., Metekia, A.S., Stabel, J.R., Al-Majali, A.M., Lafi, S.L. 2010. Pathology of subclinical paratuberculosis (Johne's Disease) in Awassi sheep with reference to its occurrence in Jordan. International Journal for Veterinary and Biomedical Science. 55(12):590-602.

Han, J., Rutherford, M.S., Faaberg, K.S. 2010. Proteolytic products of the porcine reproductive and respiratory syndrome virus nsp2 replicase protein. Journal of Virology. 84(19):10102-10112.

Herzig, C., Waters, W.R., Baldwin, C., Telfer, J. 2010. Evolution of the CD163 Family and its Relationship to the Bovine Gamma Delta T Cell Co-receptor WC1. BMC Evolutionary Biology. 10(1):181.

Huang, L.V., Zhai, S.L, Cheung, A.K., Zhang, H.B., Long, J.X., Yuan, S.S. 2010. Detection of a novel porcine parvovirus, PPV4, in Chinese swine herds. Virology Journal. 7(1):333.

Janagama, H.K., Lamont, E.A., George, S., Bannantine, J.P., Xu, W., Tu, Z.J., Wells, S.J., Schefers, J., Sreevatsan, S. 2010. Primary transcriptomes of Mycobacterium avium subsp. paratuberculosis reveal proprietary pathways in tissue and macrophages. Biomed Central (BMC) Genomics. 11(1):561.

Jensen, A.E., Halling, S.M. 2010. Effect of Polymyxin B and Environmental Conditions on Isolation of Brucella Species and the Vaccine Strain RB51. Comparative Immunology Microbiology and Infectious Diseases. 33(2):121-131.

Lippolis, J.D., Reinhardt, T.A. 2010. Utility, Limitations, and Promise of Proteomics in Animal Science. Veterinary Immunology and Immunopathology. 138(4):241-251.

Lo, M., Murray, G., Khoo, C.A., Haake, D., Zuerner, R.L., Adler, B. 2010. Transcriptional response of Leptospira interrogans to iron limitation and characterization of a PerR homolog. Infection and Immunity. 78(11):4850-4859.

Loiacono, C.M., Beckwith, N., Kunkle, R.A., Orcutt, D., Hall, S.M. 2010. Detection of PrPSc in Formalin-Fixed, Paraffin Embedded Tissue by Western Blot Differentiates Classical Scrapie, Nor98 Scrapie, and Bovine Spongiform Encephalopathy. Journal of Veterinary Diagnostic Investigation. 22(5):684-689.

Lorusso, A., Faaberg, K.S., Killian, M., Koster, L., Vincent, A.L. 2010. One-Step Real-Time RT-PCR for Pandemic Influenza A Virus (H1N1) 2009 Matrix Gene Detection in Swine Samples. Journal of Virological Methods. 164(1-2):83-87.

Loving, C.L., Brockmeier, S.L., Vincent, A.L., Palmer, M.V., Sacco, R.E., Nicholson, T.L. 2010. Influenza Virus Coinfection with Bordetella bronchiseptica Enhances Bacterial

Colonization and Host Responses Exacerbating Pulmonary Lesions. Microbial Pathogenesis. 49(5):237-245.

Ma, W., Lager, K.M., Lekcharoensuk, P., Ulery, E.S., Janke, B.H., Solorzano, A., Webby, R.J., Garcia-Sastre, A., Richt, J.A. 2010. Viral Reassortment and Transmission after Coinfection of Pigs with Classical H1N1 and Triple Reassortant H3N2 Swine Influenza Viruses. Journal of General Virology. 91(Pt 9):2314-2321.

Ma, W., Vincent, A.L., Lager, K.M., Janke, B.H., Henry, S.C., Rowland, R.R., Hesse, R.A., Richt, J.A. 2010. Identification and Characterization of a Highly Virulent Triple Reassortant H1N1 Swine Influenza Virus in the United States. Virus Genes. 40(1):28-36.

McClenahan, S.D., Bok, K., Sosnovtsev, S.V., Neill, J.D., Burek, K.A., Beckmen, K.B., Green, K.Y., Romero, C.H. 2010. Expression and Self-Assembly of Virus-Like Particles from Two Genotypes of Marine Vesiviruses and Development of an ELISA for the Detection of Antibodies. Veterinary Microbiology. 142(3-4):184-192.

Metwally, S., Mohamed, F., Faaberg, K., Burrage, T., Prarat, M., Moran, K., Bracht, A., Mayr, G., Berninger, M., Koster, L., To, T.L., Nguyen, V.L., Reising, M., Landgraf, J., Cox, L., Lubroth, J., Carrillo, C. 2010. Pathogenicity and molecular characterization of emerging porcine reproductive and respiratory syndrome virus in Vietnam in 2007. Transboundary and Emerging Diseases. 57(5):315-329.

Miller, L.C., Neill, J.D., Harhay, G.P., Lager, K.M., Laegreid, W.W., Kehrli, Jr., M.E. 2010. In-depth global analysis of transcript abundance levels in porcine alveolar macrophages following infection with porcine reproductive and respiratory syndrome virus. Advances in Virology. 2010: Article ID 864181, 12 pages. doi:10.1155/2010/864181.

Miller, L.C., Zanella, E.L., Waters, W.R., Lager, K.M. 2010. Cytokine Protein Expression Levels in Tracheobronchial Lymph Node Homogenates of Pigs Infected with Pseudorabies Virus. Clinical and Vaccine Immunology. 17(5):728-734.

Nelson, C.D., Reinhardt, T.A., Beitz, D.C., Lippolis, J.D. 2010. In vivo activation of the intracrine vitamin D pathway in innate immune cells and mammary tissue during a bacterial infection. PLoS ONE. 5(11):e15469.

Nelson, C.D., Reinhardt, T.A., Thacker, T.C., Beitz, D.C., Lippolis, J.D. 2010. Modulation of the Bovine Innate Immune Response by Production of 1alpha,25-Dihydroxyvitamin D3 in Bovine Monocytes. Journal of Dairy Science. 93(3):1041-1049.

Nonnecke, B.J., Foote, M.R., Miller, B.L., Beitz, D.C., Horst, R.L. 2010. Short Communication: Fat-Soluble Vitamin and Mineral Status of Milk Replacer-Fed Dairy Calves: Effect of Growth Rate during the Preruminant Period. Journal of Dairy Science. 93(6):2684-2690.

Olsen, S.C. 2010. Brucellosis in the United States: Role and Significance of Wildlife Reservoirs. Vaccine. 28(S5):F73-F76.

Olsen, S.C., Tatum, F.M. 2010. Bovine Brucellosis. Veterinary Clinics of North America. 26(1):15-27.

Pithua, P., Wells, S.J., Godden, S.M., Sreevatsan, S., Stabel, J.R. 2010. Experimental Validation of a Nested Polymerase Chain Reaction Targeting the Genetic Element ISMAP02 for Detection of Mycobacterium avium subspecies paratuberculosis in Bovine Colostrum. Journal of Veterinary Diagnostic Investigation. 22(2):253-256.

Porter, B.F., Ridpath, J.F., Calise, D.V., Payne, H.R., Janke, J.J., Baxter, D.G., Edwards, J.F. 2010. Hypomyelination Associated with Bovine Viral Diarrhea Virus Type 2 Infection in a Longhorn Calf. Veterinary Pathology. 47(4):658-663.

Register, K.B., Nicholson, T.L., Guthrie, J.L. 2010. Evaluation of the Specificity of BP3385 for Bordetella pertussis. Journal of Clinical Microbiology. 48(9):3334-3337.

Reinhardt, T.A., Lippolis, J.D., Mccluskey, B.J., Goff, J.P., Horst, R.L. 2010. Prevalence of Subclinical Hypocalcemia in Dairy Herds. The Veterinary Journal. doi: 10.1016/j.tvjl.2010.03.025.

Ridpath, J.F., Dominowski, P., Mannan, R., Yancey Jr, R., Jackson, J.A., Taylor, L., Mediratta, S., Eversole, R., Mackenzie, C.D., Neill, J.D. 2010. Evaluation of Three Experimental Bovine Viral Diarrhea Virus Killed Vaccines Adjuvanted with Combinations of QuilA Cholesterol and Dimethyldioctadecylammonium (DDA) Bromide. Veterinary Research Communications. 34(8):691-702.

Ridpath, J.F., Fulton, R.W., Kirkland, P.D., Neill, J.D. 2010. Prevalence and Antigenic Differences Observed between Bovine Viral Diarrhea Virus Subgenotypes Isolated from Cattle in Australia and Feedlots in the Southwestern United States. Journal of Veterinary Diagnostic Investigation. 22(2):184-191.

Schiller, I., Oesch, B., Vordermeier, H.M., Palmer, M.V., Harris, B.N., Orloski, K.A., Buddle, B.M., Thacker, T.C., Lyashchenko, K.P., Waters, W.R. 2010. Bovine Tuberculosis: A Review of Current and Emerging Diagnostic Techniques in View of their Relevance for Disease Control and Eradication. Transboundary and Emerging Diseases. 57(4):205-220.

Schiller, I., Vordermeier, H.M., Waters, W.R., Kyburz, A., Cagiola, M., Whelan, A., Palmer, M.V., Thacker, T.C., Meijlis, J., Carter, C., Egnuni, T., Hardegger, R., Marg-Hauffe, B., Raeber, A., Oesch, B. 2010. Comparison of Tuberculin Activity in the Interferon-gamma Assay for the Diagnosis of Bovine Tuberculosis. Veterinary Record. 167(9):322-326.

Schiller, I., Vordermeier, H.M., Waters, W.R., Whelan, A.O., Coad, M., Gormley, E., Buddle, B.M., Palmer, M.V., Thacker, T.C., Mcnair, J., Welsh, M., Hewinson, R.G., Oesch,

B. 2010. Bovine Tuberculosis: Effect of the Tuberculin Skin Test on In vitro Interferon gamma Responses. Veterinary Immunology and Immunopathology. 136(1-2):1-11.

Schloss, P.D., Allen, H.K., Klimowicz, A.K., Mlot, C., Gross, J.A., Savengsuksa, S., Mcellin, J., Clardy, J., Ruess, R.W., Handelsman, J. 2010. Psychrotrophic Strain of Janthinobacterium lividum from a Cold Alaskan Soil Produces Prodigiosin. DNA and Cell Biology. 29(9). Available: http://www.liebertonline.com/doi/full/10.1089/dna.2010.1020.

Sharma, V.K., Bearson, S.M., Bearson, B.L. 2010. Evaluation of the Effects of SDIA, a LUXR Homologue, on Adherence and Motility of Escherichia coli O157:H7. Microbiology. 156(5):1303-1312.

Scott, M.C., Bannantine, J.P., Kaneko, Y., Branscum, A.J., Whitlock, R.H., Mori, Y., Speer, C.A., Eda, S. 2010. Absorbed EVELISA: a diagnostic test with improved specificity for Johne's Disease in cattle. Foodborne Pathogens and Disease. 7(11):1291-1296.

Tabatabai, L.B., Zimmerli, M.K., Zehr, E.S., Briggs, R.E., Tatum, F.M. 2010. Ornithobacterium rhinotracheale North American Field Isolates Express a Hemolysin-Like Protein. Avian Diseases. 54(3):994-1001.

Vincent, A.L., Ciacci-Zanella, J.R., Lorusso, A., Gauger, P.C., Zanella, E.L., Kehrli Jr, M.E., Janke, B.H., Lager, K.M. 2010. Efficacy of Inactivated Swine Influenza Virus Vaccines Against the 2009 A/H1N1 Influenza Virus in Pigs. Vaccine 28(15):2782-2787.

Wang, B., Wesley, I.V., Mckean, J.D., O'Connor, A.M. 2010. Sub-iliac Lymph Nodes at Slaughter Lack Ability to Predict Salmonella-enteric Prevalence for Swine Farms. Foodborne Pathogens and Disease. 7(7):795-800.

Waters, W.R., Palmer, M.V., Thacker, T.C., Davis, W.C., Sreevatsan, S., Coussens, P., Meade, K.G., Hope, J.C., Estes, D.M. 2010. Tuberculosis immunity: Opportunities from studies with cattle. Clinical and Developmental Immunology. 2011:01-11.

Waters, W.R., Whelan, A.O., Lyashchenko, K.P., Greenwald, R., Palmer, M.V., Harris, N.B., Hewinson, R.G., Vordermeier, H.M. 2010. Immune Responses in Cattle Inoculated with Mycobacterium bovis, Mycobacterium tuberculosis, or Mycobacterium kansasii. Clinical and Vaccine Immunology. 17(2):247-252.

Xiong, N., Brewer, M., Day, T.A., Kimber, M.J., Barnhill, A.E., Carlson, S.A. 2010. Evaluation of the pathogenicity and virulence of three strains of Salmonella organisms in calves and pigs. American Journal of Veterinary Research. 71(10):1170-1177.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

[*] Including viruses and prions.

I. Objectives:
Provide scientific information to solutions in the control and eradication of national and international exotic, emerging, zoonotic, and endemic infectious diseases of animals through a comprehensive research program emphasizing basic and applied research in diagnostics, prevention, and control strategies, prediction of disease outbreaks, molecular epidemiology, and understanding disease pathogenesis.

The objectives of the research programs are to produce new research knowledge and technology to:

- prevent, reduce or eliminate losses from impaired performance, and increased deaths and condemnations;
- develop more sensitive, specific and faster diagnostic tests;
- develop vaccines designed for the control and, when feasible, the eradication of disease;
- improve our understanding of the ecology and epidemiology of pathogens at the domestic-wild life interface; and
- improve our understanding of the genetic and pathobiological basis of virulence.

This research provides government regulatory agencies and the livestock industries with improved intervention strategies against priority diseases.

II. Agents Microorganisms and/or Toxins:

- **Overlap Select Agents**
  Including NIAID Category B Priority Pathogens
- **USDA Select Agents and Toxins**
- **Other pathogens or toxins**
  Including non-Select Agent, NIAID Category B and C Priority Pathogens

The agents studied are endemic and emerging viruses and bacteria that cause diseases in livestock and poultry. The majority of the agents studied are not classified by USDA as select agents. The agents classified as select agents are pathogens that are zoonotic agents (diseases transmitted from animals to people) that pose a threat to our animal production systems, our agricultural economy, and agricultural exports.

III. Outdoor Studies:
No research work is done outdoors with infectious organisms. Outdoor studies are conducted only for ecological purposes and monitoring of bacteria, viruses, and prions in wild life.

Form A, Part 2 (iii)

National biological defence research and development programme

III. Facilities

1. What is the name of the facility?

Southeast Poultry Research Laboratory

2. Where is it located (provide both address and geographical location)?

Agricultural Research Service, United States Department of Agriculture
934 College Station Road
Athens, Georgia 30605

3. Floor area of laboratory areas by containment level.

BL2 (sqM)	1138
BL3 (sqM)	624
BL4 (sqM)	0
Total (sqM)	1762

4. The organizational structure of each facility.

I Total Number of Personnel 43

II Division of Personnel:

Military	0
Civilian	43

III Division of Personnel by Category:

Scientists	11
Engineers	0
Technicians	19
Administrative/Support	13

IV List the scientific disciplines represented in the scientific/engineering support staff.

Animal Science
Biochemistry
Biology
Biotechnology
Cell Biology

Clinical Immunology
Computational Biology
Genetics
Genomics
Immunology
Infectious Disease
Microbiology
Molecular Biology
Molecular Computational Biology
Pathogenesis
Pathology
Proteomics
Public Health
Statistics
Vaccine Evaluation
Veterinarian
Veterinary Clinical Research
Veterinary Medicine
Virology

V Are contractor staff working in the facility? If so, provide an approximate number.

Yes Number: 3

VI What is (are) the source(s) of funding for the work conducted in the facility, including indication if activity is wholly or partly financed by the Ministry of Defence?

U.S. Department of Agriculture (USDA)
Centers for Disease Control and Prevention (CDC)
U.S. Department of Defense (DOD)
Non-profit Associations
Private Sector Companies
National Institutes of Health (NIH)
Other Governmental Agencies

VII What are the funding levels for the following program areas:

Research	$5,800,000
Development	$ 0
Test and evaluation	$ 0
Total	$5,800,000

VIII Briefly describe the publication policy of the facility:

All scientific research data is available for publication in peer-reviewed publications after review for dual use determination. All scientists are required to have minimum of two peer-reviewed publications per year. They are encouraged to present research at scientific conferences and publish in books and proceedings.

No classified research is conducted at this facility.

IX Provide a list of publicly-available papers and reports resulting from the work during the previous 12 months. (To include authors, titles, and full references.)

Abbas, M.A., Spackman, E., Swayne, D.E., Ahmed, Z., Sarmento, L., Siddique, N., Naeem, K., Hameed, A., Rehmani, S. 2010. Sequence and phylogenetic analysis of H7N3 avian influenza viruses isolated from poultry in Pakistan 1995-2004. Virology Journal. 7:137.

Arafa, A., Suarez, D.L., Aly, M.M., Hassan, M.K. 2010. Phylogenetic analysis of hemagglutinin and neuraminidase genes of highly pathogenic avian influenza H5N1 Egyptian strains isolated from 2006 to 2008 indicates heterogeneity with multiple distinct sublineages. Avian Diseases. 54:345-349.

Avellaneda, G.E., Mundt, E., Lee, C., Jadhao, S., Suarez, D.L. 2010. Differentiation of infected and vaccinated animals (DIVA) using the NS1 protein of avian influenza virus. Avian Diseases. 54:278-286.

Avellaneda, G.E., Sylte, M.J., Lee, C., Suarez, D.L. 2010. A heterologous neuraminidase subtype strategy for the differentiation of infected and vaccinated animals (DIVA) for avian influenza virus using an alternative neuraminidase inhibition test. Avian Diseases. 54:272-277.

Belser, J.A., Wadford, D.A., Pappas, C., Gustin, K.M., Maines, T.R., Pearce, M.B., Zeng, H., Swayne, D.E., Pantin Jackwood, M.J., Katz, J.M., Tumpey, T.M. 2010. Pathogenesis of pandemic influenza A (H1N1) and triple-reassortant swine influenza A (H1) viruses in mice. Journal of Virology. 84(9):4194-4203.

Cilloniz, C., Pantin Jackwood, M.J., Ni, C., Goodman, A.G., Peng, X., Proll, S.C., Carter, V.S., Rosenzweig, E.R., Szretter, K.J., Katz, J.M., Korth, M.J., Swayne, D.E., Tumpey, T.M., Katze, M.G. 2010. Lethal dissemination of H5N1 influenza virus is associated with dysregulation of inflammation, hematological function and lipoxin signaling in a mouse model of infection. Journal of Virology. 84(15):7613-7624.

Coffee, L.L., Hanson, B.A., Luttrell, M., Swayne, D.E., Senne, D.A., Goekjian, V.H., Niles, L.J., Stallknecht, D.E. 2010. Avian paramyxoviruses in charadriiform birds. Journal of Wildlife Diseases. 46(2):481-487.

Day, J.M., Ballard, L.L., Duke, M.V., Scheffler, B.E., Zsak, L. 2010. Metagenomic analysis of the turkey gut RNA virus community. Virology Journal. 7:313.

Day, J.M., Zsak, L. 2010. Determination and analysis of the full-length chicken parvovirus genome. Virology. 399(1):59-64.

Eggert, D.L., Thomas, C., Spackman, E., Pritchard, N., R0jo, F., Bublot, M., Swayne, D.E. 2010. Characterization and efficacy determination of commercially available Central American H5N2 avian influenza vaccines for poultry. Vaccine. 28:4609-4615.

Jackwood, M., Suarez, D.L., Hilt, D., Pantin Jackwood, M.J., Woolcock, P., Cardona, C. 2010. Biologic characterization of chicken-derived H6N2 low pathogenic avian influenza viruses in chickens and ducks. Avian Diseases. 54:120-125.

Jadhao, S., Suarez, D.L. 2010. New approach to delist highly pathogenic avian influenza viruses from BSL3+ select agents to BSL2 non-select status for diagnostics and vaccines. Avian Diseases. 54:302-306.

Khan, T.A., Rue, C.A., Rehmani, S.F., Ahmed, A., Wasilenko, J.L., Miller, P.J., Afonso, C.L. 2010. Phylogenetic and pathological characterization of Newcastle disease virus isolates from Pakistan. Journal of Clinical Microbiology. 48(5):1892-1894.

Kuiken, T., Van Den Brand, J., Van Riel, D., Pantin Jackwood, M.J., Swayne, D.E. 2010. Comparative pathology of select agent influenza A virus infections. Veterinary Pathology. 47(5):893-914.

Kwon, Y., Thomas, C., Swayne, D.E. 2010. Variability in pathobiology of South Korean H5N1 high-pathogenicity avian influenza virus infection for 5 species of migratory waterfowl. Veterinary Pathology. 47(3):495-506.

Liljebjelke, K.A., Petkov, D., Kapczynski, D.R. 2010. Mucosal vaccination with a codon-optimized hemagglutinin gene expressed by attenuated Salmonella elicits a protective immune response in chickens against highly pathogenic avian influenza. Vaccine. 28(27):4430-4437.

Lira, J., Moresco, K.A., Stallknecht, D., Swayne, D.E., Fisher, D.S. 2010. Single and combination diagnostic test efficiency and cost analysis for detection and isolation of avian influenza virus from wild bird cloacal swabs. Avian Diseases. 54:606-612.

Liu, Y., Mundt, E., Mundt, A., Sylte, M.J., Suarez, D.L., Swayne, D.E., Garcia, M. 2010. Development and evaluation of an avian influenza, neuraminidase subtype 1, indirect enzyme-linked immunosorbent assay for poultry using the differentiation of infected from vaccinated animals control strategy. Avian Diseases. 54:613-621.

Marusak, R.A., Guy, J.S., Abdul-Aziz, T.A., West, M.A., Fletcher, 0.J., Day, J.M., Zsak, L.,

Barnes, H.J. 2010. Parvovirus associated cerebellar hypoplasia in day-old chickens. Avian Diseases. 54:156-160.

Miller, P.J., Afonso, C.L., Spackman, E., Scott, M.A., Pedersen, J.C., Senne, D.A., Brown, J.D., Fuller, C.M., Uhart, M.M., Karesh, W.B., Brown, I.H., Alexander, D.J., Swayne, D.E. 2010. Evidence for a new avian paramyxovirus serotype-10 detected in Rockhopper penguins from the Falkland Islands. Journal of Virology. 84(21):11496-11504.

Miller, P.J., Decanini, E.L., Afonso, C.L. 2010. Newcastle disease: Evolution of genotypes and the related diagnostic challenges. Infection, Genetics and Evolution. 10(1):26-35.

Moresco, K.A., Stallknecht, D., Swayne, D.E. 2010. Evaluation and attempted optimization of avian embryos and cell culture methods for efficient isolation and propagation of low pathogenicity avian influenza viruses. Avian Diseases. 54:622-626.

Pantin Jackwood, M.J., Wasilenko, J.L., Spackman, E., Suarez, D.L., Swayne, D.E. 2010. Susceptibility of turkeys to pandemic H1N1 virus by reproductive tract insemination. Virology Journal. 7:27.

Pedersen, J., Killian, M., Hines, N., Senne, D., Panigrahy, B., Ip, H., Spackman, E. 2010. Validation of a real-time reverse transcriptase-PCR assay for the detection of H7 avian influenza virus. Avian Diseases. 54:639-643.

Pfeiffer, J., Suarez, D.L., Sarmento, L., To, T., Nguyen, T., Pantin Jackwood, M.J. 2010. Efficacy of commercial vaccines in protecting chickens and ducks against H5N1 highly pathogenic avian influenza viruses from Vietnam. Avian Diseases. 54:262-271.

Pillai, S.P., Pantin Jackwood, M.J., Suarez, D.L., Lee, C. 2010. Pathobiological characterization of low-pathogenicity H5 avian influenza viruses of diverse origins in chickens, ducks and turkeys. Archives of Virology. 115:1439-1451.

Pillai, S.S., Pantin Jackwood, M.J., Yassine, H., Saif, Y.M., Lee, C. 2010. The high susceptibility of turkeys to influenza viruses of different origins implies their importance as potential intermediate host. Avian Diseases. 54:522-526.

Roth, J.P., Li, J.K., Barnard, D.L. 2010. Human parainfluenza virus type 3 (HPIV-3); Construction and rescue of an infectious, recombinant virus expressing the enhanced green fluorescent protein (EGFP). Curr. Protoc. Microbiol. 17; 15F.1.1-15F.1.22.

Rue, C.A., Susta, L., Brown, C.C., Pasick, J.M., Swafford, S.R., Wolf, P.C., Killian, M.L., Pedersen, J.C., Miller, P.J., Afonso, C.L. 2010. Evolutionary changes effecting rapid diagnostics of 2009 Newcastle disease viruses isolated from Double-crested Cormorants. Journal of Clinical Microbiology. 48(7):2440-2448.

Sarmento, L., Wasilenko, J.L., Pantin Jackwood, M.J. 2010. The effects of NS gene

exchange on the pathogenicity of H5N1 HPAI viruses in ducks. Avian Diseases. 54:532-537.

Slomka, M., Densham, A., Coward, V.J., Essen, S., Brookes, S.M., Irvine, R.M., Spackman, E., Ridgeon, J., Gardner, R., Hanna, A., Suarez, D.L., Brown, I. 2010. Real time reverse transcription (RRT)-polymerase chain reaction (PCR) methods for detection of pandemic (H1N1) 2009 influenza virus and European swine influenza A virus infections in pigs. Influenza and Other Respiratory Viruses. 4:277-293.

Spackman, E., Day, J.M., Pantin Jackwood, M.J. 2010. Astrovirus, reovirus and rotavirus concomitant infection causes decreased weight gain in broad-breasted white poults. Avian Diseases. 54:16-21.

Spatz, S.J. 2010. Accumulation of attenuating mutations in varying proportions within a high passage very virulent plus strain of gallid herpesvirus type 2.Virus Res 149(2):135-42.

Stittelaar, K.J., Lacombe, V., Van Lavieren, R., Van Amerongen, G., Simon, J., Cozette, V., Swayne, D.E., Poulet, H., Osterhaus, A.D. 2010. Cross-cloade immunity in cats vaccinated with a canarypox-vectored avian influenza vaccine. Vaccine. 28(31):4970-4976.

Tibbetts, C., Borsuk, L., Lichanska, A., Lorence, M., Weslowski, B., Schafer, K., Stenger, D., Lin, B., Malanowski, A., Wang, Z., Blaney, K., Long, N., Schnur, J., Metzgar, D., Myers, C., Faix, D., Russell, K., Brown, J., Saad, M., Thomas, C., Swayne, D.E. 2010. Simultaneous detection and identification of influenza virus types, subtypes and emergent variants using re-sequencing microarrays. PLOS One 5(2):e8995, doi:10.1371/journal.pone.0008995.

Van Borm, S., Suarez, D.L., Boschmans, M., Ozhelvaci, O., Van Den Berg, T.P. 2010. Rapid detection of Eurasian and American H7 subtype influenza A viruses using a single TaqManMGB real-time RT-PCR. Avian Diseases. 54:632-638.

Wasilenko, J.L., Sarmento, L., Spatz, S.J., Pantin Jackwood, M.J. 2010. Cell surface display of highly pathogenic avian influenza hemagglutinin on the surface of Pichia pastoris cells using alpha-agglutinin for production of oral vaccines. Biotechnology Progress. 26(2):542-547.

5. Briefly describe the biological defence work carried out at the facility, including type(s) of microorganisms[*] and/or toxins studied, as well as outdoor studies of biological aerosols.

I. Objectives:
Provide scientific solutions to national and international exotic, emerging and endemic poultry viral diseases through a comprehensive research program emphasizing basic and applied research in diagnostics, prevention, and control strategies, prediction of disease

[*] Including viruses and prions.

outbreaks, molecular epidemiology, and understanding disease pathogenesis.

The objectives of the research program are to produce new research knowledge and technology to:

- prevent, reduce or eliminate losses from impaired performance and increased deaths and condemnations;
- develop more sensitive, specific and faster diagnostic tests;
- develop vaccines designed for the control and, when feasible, the eradication of disease;
- improve our understanding of the ecology and epidemiology of viruses at the wild bird-domestic poultry interface; and
- improve our understanding of the genetic and pathobiological basis of virulence.

This research provides government regulatory agencies and the poultry industries with improved intervention strategies against poultry viral diseases. The Laboratory has two research units: 1) Exotic and Emerging Avian Viral Diseases Research Unit, and 2) Endemic Poultry Viral Diseases Research Unit.

II. Agents Microorganisms and/or Toxins:

- **USDA Select Agents and Toxins**
- **Other pathogens or toxins**

  Including non-Select Agent, NIAID Category B and C Priority Pathogens

The agents studied are foreign and emerging viruses that cause diseases in poultry. The majority of the agents studied are classified by USDA as select agents. Some of the agents classified as select agents are pathogens that are zoonotic agents (diseases transmitted from animals to people) that pose a threat to our poultry production systems, our agricultural economy, and agricultural exports.

III. Outdoor Studies:

No research work is done outdoors with infectious organisms. Outdoor studies are conducted only for ecological purposes and monitoring of viruses in free flying wild birds.

Form B

BWC - Confidence Building Measure

Exchange of Information on all Outbreaks of Infectious Diseases and Similar Occurrences Caused by Toxins

United States of America

April 15, 2011

Form B(i)

BWC - Confidence Building Measure

Background Information on Outbreaks of Reportable Infectious Diseases

United States of America

April 15, 2011

Form B (i)

Background Information on Outbreaks of Reportable Infectious Diseases

Human Disease	2006	2007	2008	2009	2010
Anthrax	1	1	---	---	---
Botulism, Total	165	144	145	96	101
Botulism, Foodborne	20	32	17	11	6
Botulism, Infant	97	85	109	62	69
Brucellosis	121	131	80	110	2,403
California serogroup virus disease	67	55	62	47	71
Chancroid	33	23	25	46	36
Cholera	9	7	5	8	8
Cyclosporiasis	137	93	139	127	167[1]
Diphtheria	---	---	---	---	---
Domestic arboviral diseases					[2]
Eastern equine encephalitis virus disease	8	4	4	4	10
Haemophilus influenzae, invasive disease (age <5 yrs):					
Nonserotype b	175	199	244	215	148
Serotype b	29	22	30	27	16
Unknown serotype	179	180	163	230	254
Hansen Disease	66	101	80	62	57[3]
Hantavirus pulmonary syndrome	40	32	18	13	17[4]
Hemolytic uremic syndrome, postdiarrheal	288	292	330	228	218[5]
HIV infection, pediatric (age	---	---	---	---	---[6]
Influenza-associated pediatric mortality	43	77	90	360	61
Listeriosis	884	808	759	783	746
Measles	55	43	140	65	61
Meningococcal disease, invasive:					
A, C, Y, and W-135	318	325	330	282	227
other serogroup	32	35	38	23	9
serogroup B	193	167	188	148	107
unknown serogroup	651	550	616	477	406
Mumps	6584	800	454	1444	5,528
Novel influenza A virus infections	NN	4	2	43771	4
Plague	17	7	3	8	2
Polio virus Infection, nonparalytic	NN	---	---	---	---
Poliomyelitis, paralytic	---	---	---	---	---

Powassan virus disease	NN	---	---	---	5
Psittacosis	21	12	8	9	4
Q Fever					
Total	169	171	120	101	118[7]
Acute	---	---	106	85	90
Chronic	---	---	14	16	28
Rabies, human	3	1	2	4	1
Rubella	11	12	16	3	6
Rubella Congenital Syndrome	1	---	---	1	---
SARS-CoV	---	---	---	---	---[8]
Smallpox	---	---	---	---	---
St. Louis encephalitis virus disease	10	9	13	11	8
Streptococcal toxic-shock syndrome	125	132	157	134	155
Syphilis, congenital (age	349	430	431	302	213
Tetanus	41	28	19	16	8
Toxic-shock syndrome (staphylococcal)	101	92	71	74	73[9]
Trichinellosis	15	5	39	11	4
Tularemia	95	137	123	89	109
Typhoid Fever	353	434	449	344	398
Vancomycin-intermediate Staphylococcus aureus	6	37	63	71	89[10]
Vancomycin-resistant Staphylococcus aureus	1	2	0	0	1[11]
Vibriosis (noncholera Vibrio species infections)	NN	549	588	654	756[12]
Viral Hemorrhagic Fever	NN	NN	NN	NN	1[13]
Western equine encephalitis virus disease	---	---	---	---	---
Yellow fever	---	---	---	---	---

[1] Not reportable in all states. Reporting exceptions are available at http://www.cdc.gov/osels/ph_surveillance/nndss/
[2] Includes both neuroinvasive and nonneuroinvasive. Not reportable in all states. Reporting exceptions are available at http://www.cdc.gov/osels/ph_surveillance/nndss/
[3] Not reportable in all states. Reporting exceptions are available at http://www.cdc.gov/osels/ph_surveillance/nndss/
[4] Not reportable in all states. Reporting exceptions are available at http://www.cdc.gov/osels/ph_surveillance/nndss/
[5] Not reportable in all states. Reporting exceptions are available at http://www.cdc.gov/osels/ph_surveillance/nndss/
[6] Updated monthly from reports to the Division of HIV/AIDS Prevention (CDC). Implementation of HIV reporting infulences the number of cases reported. HIV data have been temporarily suspended until upgrading of the national HIV/AIDS surveillance data management system is completed.
[7] Not reportable in all states. Reporting exceptions are available at http://www.cdc.gov/osels/ph_surveillance/nndss/
[8] Not reportable in all states. Reporting exceptions are available at http://www.cdc.gov/osels/ph_surveillance/nndss/
[9] Not reportable in all states. Reporting exceptions are available at http://www.cdc.gov/osels/ph_surveillance/nndss/
[10] Not reportable in all states. Reporting exceptions are available at http://www.cdc.gov/osels/ph_surveillance/nndss/
[11] Not reportable in all states. Reporting exceptions are available at http://www.cdc.gov/osels/ph_surveillance/nndss/
[12] Not reportable in all states. Reporting exceptions are available at http://www.cdc.gov/osels/ph_surveillance/nndss/
[13] There was one case of viral hemorrhagic fever reported in 2010. The one case was confirmed as lassa fever.

Animal Disease	2006	2007	2008	2009	2010
Amphibians					
Infection with Batrachochytrium dendrobatidis (wild species)	n/a	n/a	n/a	Yes	Yes[1]
Infection with ranavirus (wild species)	n/a	n/a	n/a	Yes	Yes[2]
Avian diseases					
Avian chlamydiosis	Yes	Yes	Yes	No	Yes[3]
Avian infectious bronchitis	Yes	Yes	Yes	Yes	Yes
Avian infectious laryngotracheitis	Yes	Yes	Yes	Yes	Yes[4]
Avian mycoplasmosis (M. gallisepticum)	Yes	Yes	Yes	Yes	Yes[5]
Avian mycoplasmosis (M. synoviae)	Yes	Yes	Yes	Yes	Yes[6]
Duck viral hepatitis	No	No	No	No	No
Fowl cholera (Pasteurella multocida)	Yes	Yes	Yes	Yes	Yes
Fowl typhoid (Salmonella gallinarum)	No	No	No	No	No
Highly pathogenic avian influenza	No	No	No	No	No
Low pathogenic avian influenza (poultry)	n/a	Yes	Yes	Yes	Yes[7]
Infectious bursal disease (Gumboro disease)	Yes	Yes	Yes	Yes	Yes
Marek's disease	Yes	Yes	Yes	Yes	Yes
Newcastle disease (Neurotropic and viscerotropic strains)	No	No	No	No	No[8]
Pullorum disease (Salmonella pullorum)	Yes	No	Yes	No	No[9]
Turkey rhinotracheitis	Yes	Yes	Yes	No	No
Bee diseases					
Acarapisosis of honey bees	Yes	Yes	Yes	Yes	Yes
American foulbrood of honey bees	Yes	Yes	Yes	Yes	Yes
European foulbrood of honey bees	Yes	Yes	Yes	Yes	Yes
Small hive beetle infestation (Aethina tumida)	Yes	Yes	Yes	Yes	Yes[10]
Tropilaelaps infestation of honey bees	No	No	No	No	No
Varroosis of honey bees	Yes	Yes	Yes	Yes	Yes
Cattle diseases					
Bovine anaplasmosis	Yes	Yes	Yes	Yes	Yes
Bovine babesiosis	No	No	No	No	No
Bovine genital campylobacteriosis	n/a	Yes	Yes	Yes	Yes
Bovine spongiform encephalopathy	Yes	No	No	No	No[11]
Bovine tuberculosis	Yes	Yes	Yes	Yes	Yes[12]
Bovine viral diarrhea	Yes	Yes	Yes	Yes	Yes
Contagious bovine pleuropneumonia	No	No	No	No	No
Enzootic bovine leukosis	Yes	Yes	Yes	Yes	Yes

Haemorrhagic septicaemia	No	No	No	No	No
Infectious bovine rhinotracheitis/ infectious pustular vulvovaginitis	Yes	Yes	Yes	Yes	Yes
Lumpy skin diseases	No	No	No	No	No
Theileriosis	No	No	No	No	No
Trichomonosis	Yes	Yes	Yes	Yes	Yes
Trypanosomosis	No	No	No	No	No
Crustaceans					
Crayfish plague (Aphanomyces astaci)	No	No	No	No	No
Infectious hypodermal and haematopoietic necrosis	No	No	No	No	No
Infectious myonecrosis	n/a	n/a	No	No	No
Spherical baculovirosis (Penaeus monodon-type baculovirus)	No	No	No	No	No
Taura syndrome	No	No	No	No	No
Tetrahedral baculovirosis (Baculovirus penaei)	No	No	No	No	No
White spot disease	No	Yes	Yes	No	No[13]
White tail disease	n/a	n/a	No	No	No
Yellow head disease	No	No	No	No	No
Equine diseases					
African horse sickness	No	No	No	No	No
Contagious equine metritis	Yes	No	Yes	Yes	Yes[14]
Dourine	No	No	No	No	No
Equine encephalomyelitis (Eastern)	Yes	Yes	Yes	Yes	Yes
Equine encephalomyelitis (Western)	No	No	No	No	No[15]
Equine infectious anemia	Yes	Yes	Yes	Yes	Yes
Equine influenza	Yes	Yes	Yes	Yes	Yes
Equine piroplasmosis	No	No	Yes	Yes	Yes[16]
Equine rhinopneumonitis	Yes	Yes	Yes	Yes	Yes
Equine viral arteritis	Yes	Yes	Yes	Yes	Yes
Glanders	No	No	No	No	No
Surra (Trypanosoma evansi)	No	No	No	No	No
Venezuelan equine encephalomyelitis	No	No	No	No	No
Fish					
Epizootic hematopoietic necrosis	No	No	No	No	No
Epizootic ulcerative syndrome	No	No	No	No	Yes[17]
Gyrodactylosis (Gyrodactylus salaries)	No	No	No	No	No
Infectious hematopoietic necrosis	Yes	Yes	Yes	Yes	Yes[18]

Infectious salmon anemia	Yes	No	No	No	No
Koi herpesvirus disease	n/a	Yes	Yes	Yes	Yes
Red sea bream iridoviral disease	No	No	No	No	No
Spring viremia of carp	No	No	No	No	No
Viral hemorrhagic septicaemia	Yes	Yes	Yes	Yes	Yes[19]
Lagomorph diseases					
Myxomatosis	No	No	No	No	No
Rabbit hemorrhagic disease	No	No	Yes	No	Yes[20]
Molluscs					
Abalone viral mortality	n/a	No	No	No	No
Infection with Bonamia exitiosus	No	No	No	No	No
Infection with Bonamia ostreae	Yes	No	No	No	No[21]
Infection with Marteilia refringens	No	No	No	No	No
Infection with Perkinsus marinus	Yes	Yes	Yes	No	Yes[22]
Infection with Perkinsus olseni	No	No	No	No	No
Infection with Xenohaliotis californiensis	Yes	No	No	No	No
Multiple species diseases					
Rabies	Yes	Yes	Yes	Yes	Yes
Aujeszky's disease	Yes	Yes	Yes	Yes	Yes[23]
Bluetongue	Yes	Yes	Yes	Yes	Yes
Brucellosis (Brucella abortus)	No	Yes	Yes	Yes	Yes[24]
Brucellosis (Brucella melitensis)	No	No	No	No	No
Brucellosis (Brucella suis)	No	Yes	Yes	Yes	Yes[25]
Crimean Congo haemorrhagic fever	No	No	No	No	No
Echinococcosis/hydatidosis	No	No	Yes	No	No[26]
Foot-and-mouth disease	No	No	No	No	No
Heartwater	No	No	No	No	No
Japanese encephalitis	No	No	No	No	No
Leptospirosis	Yes	Yes	Yes	Yes	Yes
New world screwworm	No	No	No	No	No
Old world screwworm	No	No	No	No	No
Paratuberculosis (Johne's Disease)	Yes	Yes	Yes	Yes	Yes
Q fever	Yes	Yes	Yes	Yes	Yes
Anthrax	Yes	Yes	Yes	Yes	Yes[27]
Rift Valley fever	No	No	No	No	No
Rinderpest	No	No	No	No	No
Trichinellosis	Yes	No	No	No	No[28]
Tularemia	Yes	Yes	No	Yes	Yes[29]

Vesicular stomatitis	Yes	No	No	Yes	Yes[30]
West Nile fever/encephalitis	Yes	Yes	Yes	Yes	Yes
Epizootic hemorrhagic disease (EHD)	n/a	n/a	n/a	Yes	Yes[31]
Other listed disease					
Leishmaniosis	No	No	No	No	No[32]
Camelpox	No	No	No	No	No
Sheep and goat diseases					
Caprine arthritis/encephalitis	Yes	Yes	Yes	Yes	Yes
Contagious agalactia	Yes	Yes	Yes	Yes	Yes[33]
Contagious caprine pleuropneumonia	No	No	No	No	No
Enzootic abortion of ewes (ovine chlamydiosis)	Yes	Yes	Yes	Yes	Yes
Maedi-visna	Yes	Yes	Yes	Yes	Yes
Nairobi sheep diseases	No	No	No	No	No
Ovine epididymitis (Brucella ovis)	Yes	Yes	Yes	Yes	Yes
Peste des petits ruminants	No	No	No	No	No
Salmonellosis (S. abortusovis)	No	Yes	No	No	No[34]
Scrapie	Yes	Yes	Yes	Yes	Yes
Sheep pox and goat pox	No	No	No	No	No
Swine diseases					
African swine fever	No	No	No	No	No
Classical swine fever (hog cholera)	No	No	No	No	No
Nipah virus encephalitis	No	No	No	No	No
Porcine cysticercosis	No	No	No	No	No
Porcine reproductive and respiratory syndrome	Yes	Yes	Yes	Yes	Yes
Swine vesicular disease	No	No	No	No	No
Transmissible gastroenteritis	Yes	Yes	Yes	Yes	Yes

[1] Infection with Batrachochytrium dendrobatidis (wild species): Added to OIE Reportable List in 2009
[2] Infection with ranavirus (wild species): Added to the OIE Reportable List in 2009
[3] Avian chlamydiosis: Identified sporadically in wild birds, pet birds, and backyard birds only. No commercial production flock detections in 2010.
[4] Avian infectious laryngotracheitis: Sporadic and limited distribution occurrence only (primarily vaccine related).
[5] Avian mycoplasmosis (M. gallisepticum): All commercial poultry breeding flocks are under a surveillance program to confirm infection-free status. Commercial table-egg laying flocks may be vaccinated.
[6] Avian mycoplasmosis (M. synoviae): All commercial poultry breeding flocks are under a surveillance program to confirm infection-free status.
[7] Low pathogenic avian influenza (poultry): Identified sporadically in backyard poultry and in live-bird-markets which serve local ethnic communities. No commercial production flock infection detected in 2010.
[8] Newcastle disease: USGS National Wildlife Health Center confirmed virulent Newcastle Disease virus in wild double-crested cormorants in Minnesota, North Dakota, and Wisconsin in 2010. No commercial production flock detections.
[9] Pullorum disease (Salmonella pullorum): Identified sporadically in backyard poultry. No commercial production flock detections since 1991, considered absent in commercial production flocks.
[10] Small hive beetle infestation (Aethina tumida): Sporadic occurrence with limited distribution. OIE Immediate Report May 4, 2010.

[11] Bovine spongiform encephalopathy: U.S.A. BSE status-‘Controlled Risk'. No detections reported in 2010.
[12] Bovine tuberculosis (Mycobacterium bovis) sporadic occurrence and limited distribution. Since 1994, an endemic focus of bovine tuberculosis has been recognized in free-ranging white-tailed deer (Odocoileus virginianus) in a portion of the northeastern region of the Lower Peninsula of Michigan. A focus of infection has been found in a northwestern Minnesota since 2005.
[13] White spot disease: Sporadic occurrence & limited distribution. No detections reported in 2010
[14] Contagious equine metritis (CEM): OIE Immediate Notification December 2008 and outbreak resolved December 2010.
[15] Western equine encephalomyelitis: Sporadic occurrence (uncommon). No detections reported in 2010.
[16] Equine piroplasmosis: OIE reported outbreaks 'open'.
[17] Epizootic ulcerative syndrome (EUS): Occurs sporadically in wild fish. Florida wildlife officials reported wild fish were killed by EUS in 2010. No domestic fish detections reported in 2010.
[18] Infectious hematopoietic necrosis: Sporadic occurrence with limited distribution.
[19] Viral hemorrhagic septicaemia: Sporadic occurrence with limited distribution. No domestic detections reported in 2010.
[20] Rabbit hemorrhagic disease (RHD): Detection of one RHD event in 2010. OIE Immediate Report April 22, 2010, outbreak resolved May 18, 2010.
[21] Sporadic and limited distribution (Maine) in wild molluscs. No detections reported in 2010.
[22] Infection with Perkinsus marinus: Sporadic occurrence with limited distribution in wild mollusks. No domestic detections reported in 2010.
[23] Aujeszky's disease limited to feral and/or transitional production swine. Transitional production swine are those feral swine that are captive or domestic swine that have reasonable opportunities to be exposed to feral swine. No commercial production swine herd detections in 2010.
[24] Brucellosis (Brucella abortus) primarily limited to free-ranging bison (Bison bison) and wapiti (Cervus elaphus) in Greater Yellowstone National Park area. One domestic cattle herd detection and two domestic bison herd detections in 2010.
[25] Brucellosis (Brucella suis) limited to feral and/or transitional production swine. No commercial production swine herd detections in 2010.
[26] Echinococcosis/hydatidosis: Sporadic occurrence (uncommon). No commercial livestock detections reported in 2010.
[27] Anthrax: Sporadic occurrence with limited distribution of foci primarily in Midwestern and Western U.S.
[28] Trichinellosis: Occurs sporadically in backyard raised swine and wild species. No detections reported in 2010.
[29] Tularemia (Francisella tularensis) limited primarily to wild rabbits.
[30] Vesicular stomatitis: Sporadic and limited distribution. OIE Immediate Notification May 27,2010; Resolved August 6, 2010.
[31] Epizootic hemorrhagic disease: Sporadic and limited distribution in wild ruminants (deer) and cattle.
[32] Leishmaniosis: Sporadic occurrence (uncommon). No detections reported in 2010.
[33] Contagious agalactia: Sporadic occurrence (uncommon).
[34] Salmonellosis (S. abortusovis): Sporadic occurrence (uncommon). No detections reported in 2010.

Form B (i)

Background Information on Outbreaks of Reportable Infectious Diseases

Plant Disease	2006	2007	2008	2009	2010
Guignardia citricarpa (Citrus black spot:CBS)	No	No	No	No	Yes
Candidatus Liberibacter asiaticus (Citrus greening:CG, Huanglongbing:HLB)	Yes	Yes	Yes	Yes	Yes
Elsinoe australis (Sweet orange scab:SOS)	No	No	No	No	Yes

Form B(ii)

BWC - Confidence Building Measure

Information on Outbreaks of Infectious Diseases and Similar Occurrences that Seem to Deviate from the Normal Pattern*

* Information on events reported to the World Health Organization under International Health Regulation (IHR) Public Health Emergency of International Concern (PHEIC); World Organization for Animal Health (OEI); and/or the Food and Agriculture Organization (FAO). Additional information on OIE Reportable Diseases can be found at: http://www.oie.int/wahis/public.php?page=home

United States of America

April 15, 2011

Form B (ii)

Information on outbreaks of infectious diseases and similar occurrences that seem to deviate from the normal pattern

1. **Time of cognizance of the outbreak**
   Aware of initial cases of disease on April 13, 2009; CDC lab first identified 2009 H1N1; pandemic declared by World Health Organizations on June 11, 2009. Continued circulation with other influenza strains during 2010-2011 flu season.

2. **Location and approximate area affected**
   Worldwide (over 200 countries and territories affected).

3. **Type of disease/intoxication**
   Primarily respiratory illness.

4. **Suspected source of disease/intoxication**
   Viral respiratory pathogen, evolved via novel triple-reassortant of swine, human, and avian influenza viruses.

5. **Possible causative agent(s)**
   Novel H1N1 influenza A virus.

6. **Main characteristics of systems**
   Similar to seasonal influenza virus infection-primarily respiratory illness.

7. **Detailed symptoms, when applicable**
   - respiratory: cough, runny nose, sore throat, congestion
   - circulatory: rare myocarditis
   - neurological/behavioural: rare encephalopathy
   - intestinal: occasional diarrhea and vomiting
   - other: fever, myalgias

8. **Deviation(s) from the normal pattern as regards**
   - type: novel H1N1 virus
   - development: similar
   - place of occurrence: similar
   - time of occurrence: in 2009-2010, occurred during atypical influenza months with two peaks of disease activity (in spring 2009 and fall 2009) while a typical influenza season has a single peak during a winter month. During the 2010-2011 season, the 2009 pandemic H1N1 virus is circulating in normal seasonal timeline range, as well as other influenza viruses
   - symptoms: similar
   - virulence pattern: similar - drug resistance pattern: similar (depending on comparison influenza strain)

- agent(s) difficult to diagnose: similar
- presence of unusual vectors: none
- other: in 2009-2010, distribution of illness by age group was different from seasonal influenza (2009 pandemic H1N1 influenza caused more severe illness in a younger group of people and in specific risk groups including pregnant women and Alaska Native/American Indians, and less in the elderly population). In the 2010-2011 season, infection rates are highest in patients younger than 5 and in patients 65 years of age and older, typical of a usual flu season group of people.

9. Approximate number of primary cases
Unknown

10. Approximate number of total cases
57 million (April 2009 through January 2010)

11. Number of deaths
Estimate approximately 12,500 H1N1 related deaths in the United States (between April 2009 and April 10, 2010).

12. Development of the outbreak
Disease initially in discrete areas of United States and Mexico, followed by rapid geographic spread throughout United States and world.

13. Measures taken
- Enhanced surveillance
- Implementation of appropriate infection control and non-pharmaceutical intervention strategies (such as surgical mask use, respiratory cohorting, travel advisories, and workplace or school exclusion)
- Standard of care for viral respiratory pathogens
- Antiviral distribution and use
- Rapid development and dissemination of 2009 H1N1-specific vaccine
- Comprehensive risk communication and education for public, health professionals, businesses, and other groups. 2009 H1N1 strain included as part of trivalent vaccine development for 2010-2011 flu season, and is a good match to circulating strains of H1N1.

Additional information available on the CDC website at:
http://www.cdc.gov/h1n1flu/estimates_2009_h1n1.htm and
http://www.cdc.gov/flu/

Form B (ii)

Information on outbreaks of infectious diseases and similar occurrences that seem to deviate from the normal pattern

On July 23, 2010, the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) confirmed the identification of the fungal pathogen, *Elsinoe australis*, causal agent of sweet orange scab (SOS), on residential lemon and tangerine trees in Harris County, Texas. Citrus samples were initially collected as part of the annual citrus commodity survey performed under a cooperative agreement with Texas A&M University through the Citrus Health Response Program (CHRP). The detections in Harris County were approximately 320 miles from the lower Rio Grande Valley where most of the commercial citrus production in Texas is located. This was the first confirmation of SOS in the United States.

Surveys completed within 1-square mile of the initial detection resulted in 6 additional SOS detections on citrus trees located on 4 separate residential properties; all in close proximity to the initial Harris County detection. As part of a citrus commodity survey, a small farm located in Orange County, Texas, was also found to have infested Satsuma trees. The detection in Orange County was located 100-miles east of the initial find.

Since late July 2010, detections have also been confirmed in Louisiana and Mississippi.

On December 22, 2010, APHIS issued Federal Order DA-2010-62 to establish restrictions on the interstate movement of certain regulated articles from the States of Louisiana, Mississippi, and Texas.

Under the International Plant Protection Convention standards, *E. australis* is considered to be a pest that is transient, actionable, and under surveillance.

The report was created based on several notices issued by APHIS. The link to the disease is: http://www.aphis.usda.gov/plant_health/plant_pest_info/citrus/sweet_orange.shtml

Form B (ii)

Information on outbreaks of infectious diseases and similar occurrences that seem to deviate from the normal pattern

On April 7, 2010, the U.S. Department of Agriculture, Animal and Plant Health Inspection Service (APHIS) confirmed the first U.S. detection of *Guignardia citricarpa (citrus black spot* [CBS]) on citrus fruit from a commercial orange grove in Collier County, Florida. APHIS and the Florida Department of Agriculture and Consumer Services' Division of Plant Industry immediately began surveying the area to determine the extent of the infestation, and as a result, also detected CBS in Hendry County, Florida.

CBS poses no human health threat, nor does it kill citrus trees. However, this fungal disease causes round lesions (blemishes) on the rinds of fruit making it unmarketable, causes early fruit drop, and reduces crop yield. Symptoms may also appear on leaves. All commercial citrus cultivars are susceptible to CBS to some degree with lemon and late-maturing citrus varieties being most vulnerable. The greatest risk of disease transmission is associated with the inoculum from fallen, decomposing citrus leaves and from infected nursery stock.

Following the initial detection, APHIS prohibited the interstate movement of any *Citrus* spp. plants or plant parts from the affected groves. At the same time, APHIS prepared a draft pest risk assessment (PRA) that focused on CBS and considered all available evidence with respect to the biology of the disease. Although the PRA concluded that citrus fruit is not a significant pathway for CBS spread, a peer review of the PRA's findings is underway. APHIS will carefully consider all of the comments received from the peer reviewers and, if necessary, make changes to the PRA and to the current regulatory framework.

APHIS has issued Federal Domestic Quarantine Order DA-2010-47, which outlines requirements to allow the interstate movement of citrus fruit from the quarantine and regulated areas. This interim action will provide immediate relief to impacted citrus fruit growers and packers and protect citrus- producing States and trading partners from CBS. Specifically, as a condition of moving fruit interstate, fruit must be packed in commercial citrus packinghouses operating under compliance agreement with APHIS. The fruit must also be disinfected and shipped with limited permits. APHIS inspectors will monitor packinghouses to ensure that the conditions in the compliance agreements are fully satisfied.

The report was created based on several notices issued by APHIS. The link to the disease is: http://www.aphis.usda.gov/plant_health/plant_pest_info/citrus/black_spot.shtml

Form B (ii)

Information on outbreaks of infectious diseases and similar occurrences that seem to deviate from the normal pattern

There were five World Organization for Animal Health (OIE) immediate reports for animal disease events in 2010 (deviate from normal pattern), and three (2-equine piroplasmosis; 1 contagious equine metritis) ongoing open reports from 2009. Event summary can be found on the OIE Web site:
http://www.web.oie.int/wahis/public.php?page=home

Summary of reports:

1) Rabbit Hemorrhagic Disease (OIE Immediate Report April 22, 2010 - Resolved May 18, 2010). Rabbit hemorrhagic disease (RHD) is a highly contagious and fatal disease of wild and domestic European rabbits (*Oryctolagus cuniculus*) older than 2 months. RHD is caused by a calicivirus (genus *Lagovirus*, family Caliciviridae), a non-enveloped small round RNA virus with only one major capsid protein (VP60) (Capucci *et al.*,1990; Meyers *et al.*, 1991; Ohlinger *et al.*, 1990).

- On April 20, 2010, rabbit hemorrhagic disease was confirmed in Pine County, Minnesota. Donated rabbits were received at a wildlife center, then transferred to the index premises, a private residence, where they lived until needed as a food source at the wildlife center. Twenty rabbits died acutely at the index premises, as did all new rabbits brought to the index premises. Environmental surveillance at the index premises and the wildlife center was attempted, but no wild rabbits were captured by trapping or detected by thermal imaging. Note: In Minnesota, the predominant wild rabbits are eastern cottontails and black-tailed jackrabbits, not known to be susceptible to rabbit hemorrhagic disease. The source of the event is unknown.

2) Small Hive Beetle, *Aethina tumida* (OIE Immediate Report May 4, 2010 - Declared Endemic in East Hawaii). The small hive beetle, *Aethina tumida* (Coleoptera: Nitidulidae), is a parasite and scavenger of honey bee colonies. Adults and larvae feed on honey bee brood, honey, and pollen, causing death of brood, fermenting of honey, and destruction of comb, often resulting in the full structural collapse of the nest and absconding of the colony.

- The small hive beetle, *Aethina tumida*, was first identified in an apiary in a macadamia nut orchard in Panaewa, Hawaii (new area outside the continental United States). Subsequent investigations detected the small hive beetle in several additional apiaries and wild bee populations in East Hawaii-Hilo. There were no detections or evidence of small hive beetles in West Hawaii-Kona or on the Island of Oahu. The survey results indicated that the small hive beetle infestation extended over a large portion of East Hawaii. The situation was unlikely to be resolved in the near future, and the East Hawaii region was declared endemic for small hive beetle, *Aethina tumida.*

3) Vesicular Stomatitis (OIE Immediate Report May 27, 2010 - Resolved August 6, 2010)

Vesicular stomatitis (VS) is a vesicular disease of horses, cattle, and pigs caused by vesiculoviruses of the family Rhabdoviridae.

- Vesicular stomatitis, New Jersey serotype, was confirmed in three horses in Cochise County, Arizona, on May 26, 2010. A total of four horses in Arizona on two premises were confirmed positive during the outbreak. All quarantines on vesicular stomatitis-positive premises were released by July 2, 2010.

4) Equine piroplasmosis, *Babesia caballi* - Two OIE Immediate Reports in 2010. Equine piroplasmosis is a tick-borne protozoal disease of horses, mules, donkeys, and zebra. The aetiological agents are blood parasites named *Theileria equi* and *Babesia caballi*.

In response to the South Texas equine piroplasmosis, *Theileria equi*, detections in 2009 (OIE report, Open), States began testing horses for interstate movement and movement to equine events. As a result of this testing, additional *Theileria equi* and *Babesia equi*-positive horses were identified. The first *T. equi*-positive horses detected as a result of movement testing and testing for equine events were reported in an immediate report to the OIE in 2009, and this outbreak continues into 2011. Equine piroplasmosis-positive horses detected through interstate movement testing and testing for movement to equine events are not epidemiologically linked to the South Texas outbreak, and transmission is thought to be through management practices (contaminated needles or blood transfusions) rather than by a tick vector. The first *B. equi* detections occurred in 2010 resulting in two immediate reports to the OIE:

- New Mexico *B. caballi* (OIE Immediate Report June 18, 2010 - Resolved June 18, 2010)
    - On June 18, 2010, the United States reported to the OIE that it had diagnosed equine piroplasmosis caused by *Babesia caballi* in one horse in New Mexico. The horse was detected as a result of New Mexico's equine piroplasmosis race track screening program. The horse was euthanized and the outbreak was considered resolved.
- National *B. caballi* (OIE Immediate Report July 19, 2010 - ONGOING)
    - On July 19, the United States reported a second *Babesia caballi*-positive Quarter Horse in New Mexico. A total of four *B. caballi*-positive horses were reported to the OIE in 2010. These cases were detected through interstate movement testing and testing for equine event in New Mexico, Texas, and Iowa. All positive horses were placed under quarantine and two horses were euthanized. This outbreak is ongoing in 2011.

5) Contagious Equine Metritis (OIE Immediate Report December 16, 2008; Resolved December 29, 2010). Contagious equine metritis is an inflammation of the endometrium of mares caused by *Taylorella equigenitalis*, which usually results in temporary infertility. It is a nonsystemic

infection, the effects of which are restricted to the reproductive tract of the mare. *Taylorella equigenitalis* is most frequently transmitted by sexual contact with carrier stallions, which are always asymptomatic.

Form C

BWC - Confidence Building Measure

Encouragement of Publication of Results and Promotion of Use of Knowledge

United States of America

April 15, 2011

FORM C

Encouragement of Publication of Results and Promotion of Use of Knowledge

U.S. Department of Health and Human Services (HHS) Open Government Plan and the HHS Strategic Plan 2010-2015

The U.S. Department of Health and Human Services (HHS) Open Government Plan represents the official response of the U.S. Department of Health and Human Services (HHS) to the White House's Open Government Directive, issued on December 8, 2009. The plan embraces the idea of working proactively and energetically to advance a culture of Open Government at HHS.

HHS believes that transparency and data sharing are of fundamental importance to its ability to achieve its strategic goals of advancing the health and well-being of the United States. HHS's vast stores of data are a remarkable resource which can be utilized to help citizens understand what HHS does and hold it accountable, help the public hold the private sector accountable, increase awareness of health and human services issues, generate insights into how to improve health and well-being, spark public and private sector innovation and action, and provide the basis for new products and services.

This plan also seeks to take Open Government to the next level by expanding opportunities for public participation in HHS activities and for collaboration across HHS and with the world outside HHS - especially via the use of new information and communications technologies.

The HHS Open Government Plan is available online at:
http://www.hhs.gov/open/plan/opengovernmentplan/ourplan_openhhs.pdf

The HHS Strategic Plan 2010-2015 describes HHS' work to address complex, multifaceted, and ever-evolving health and human service issues. Goal 4 of this plan is to Increase Efficiency, Transparency, and Accountability of HHS Programs.

HHS embraces the power of Open Government, recognizing that with openness comes responsibility and accountability for results. Through Open Government, HHS is promoting transparency, participation, and collaboration-vital enablers of success in the HHS mission to improve the health and well-being of all Americans. HHS's Open Government efforts will break new ground in enabling the public to give feedback to HHS programs. HHS can help stakeholders contribute knowledge and experience to help it do jobs better, and HHS can support new kinds of collaborative teamwork that will deliver better results for our citizens. HHS will move forward toward new strategies, new tools, and a new culture of public participation and collaboration in its affairs.

The HHS Strategic Plan is available as a web document at:
http://www.hhs.gov/secretary/about/priorities/priorities.html

The Policy on Releasing and Sharing Data at the US Department of Health and Human Services (HHS) and its Components

There are a number of federally mandated regulations and clearance functions that affect the research and practice of HHS (for a list of HHS agencies and offices, please see: http://www.hhs.gov/about). They apply to all HHS employees, contractors, and awardees conducting data collection activities, whether the activities are for research or public health practice or occur in domestic or global settings. Examples include the HHS/FDA regulations for the protection of human research participants and compliance with the Federal Animal Welfare Act (AWA) as well as the Public Health Service Policy on Humane Care and Use of Laboratory Animals. In addition, the Paperwork Reduction Act (PRA), the Privacy Act, the Public Health Service Act (PHSA), the E-Government Act of 2002, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, and the Family Educational Rights and Privacy Act (FERPA) all include legislation or regulations that affect the research and public health practice.

HHS believes that public health and scientific advancement are best served when data are released to, or shared with, other public health agencies, academic researchers, and appropriate private researchers in an open, timely, and appropriate way. While recognizing the value of releasing data quickly and widely, HHS also considers the need to maintain high standards for data quality, the need for procedures that ensure that the privacy of individuals who provide personal information is not jeopardized, and the need to protect information relevant to national security, criminal investigations, or misconduct inquiries and investigations. The goal is to have a policy on data release and sharing that balances the desire to disseminate data as broadly as possible with the need to maintain high standards and protect sensitive information.

The HHS Policy on Releasing and Sharing Data is available online at:
http://www.cdc.gov/maso/Policy/ReleasingData.pdf

The National Institutes of Health (NIH) Public Access Policy

The NIH Public Access Policy ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the National Library of Medicine's digital archive PubMed Central (http://www.ncbi.nlm.nih.gov/pmc/) upon acceptance for publication. To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication.

The NIH Public Access Policy is available online at:
http://publicaccess.nih.gov/policy.htm

The National Institutes of Health (NIH) Review Mechanism for Dual Use Research Manuscripts

The NIH has established a review mechanism for manuscripts which may involve dual use research of concern.

The Publication and Abstract Clearance Form is available online at:
http://www1.od.nih.gov/oir/sourcebook/oversight/pub-clear-form.htm

The Dual Use Questionnaire is available online at:
http://sourcebook.od.nih.gov/oversight/Dual%20Use%20Questionnaire-4-2010.pdf

The US Food and Drug Administration (FDA) Publications

The FDA encourages its scientists to publish their findings in peer-reviewed science journals, books, and related articles.

A list of publications (per calendar year) covering the areas of animal health, analytical methods, and animal and food microbiology is available online at:
http://www.fda.gov/AnimalVeterinary/ScienceResearch/ResearchAreas/ucm107413.htm

A list of publications on drug development and drug interactions is available online at:
http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/DrugInteractionsLabeling/ucm091806.htm

A list of publications from the FDA's National Center for Toxicological Resarch (NCTR) is available online at:
http://www.fda.gov/AboutFDA/CentersOffices/NCTR/WhatWeDo/NCTRPublications/ucm077352.htm

A list of publications on biologic products including preventative and therapeutic vaccines, blood and blood borne products, and cell and gene therapies is available online at:
http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/ucm234680.htm

The US Food and Drug Administration (FDA) Office of Science and Engineering Laboratories (OSEL) Annual Report

The OSEL Annual Report provides current information about the Office's organization and intramural science activities; provides a summary of the Office's direct laboratory support for pre-market review and compliance cases; and provides a bibliography of scientific publications, presentations, and research seminars for the fiscal year.

Annual reports are available online at:
http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm109778.htm

The Excellence in Science Committee (EISC) at the Centers for Disease Control and Prevention (CDC)

The EISC promotes the CDC's scientific infrastructure and facilitates communication and collaboration that enhance scientific areas and activities needed for state-of-the-art conduct of science to foster, support, and protect an environment for the promotion of scientific integrity, quality assurance, and the rapid dissemination of scientific innovations, technology, and information with the ultimate goal of improving public health.

More information about the EISC is avilable online at:
http://www.cdc.gov/od/science/excellence/

The Morbidity and Mortality Weekly Report (MMWR) and Surveillance Summaries from the Centers for Disease Control and Prevention (CDC)

The MMWR series is often called "the voice of CDC." It is the agency's primary vehicle for scientific publication of timely, reliable, authoritative, accurate, objective, and useful public health information and recommendations. MMWR readership predominantly consists of physicians, nurses, public health practitioners, epidemiologists and other scientists, researchers, educators, and laboratorians. The data in the weekly MMWR are provisional, based on weekly reports to CDC by state health departments.

The Surveillance Summaries provide a means for CDC programs to disseminate surveillance findings, permitting detailed interpretation of trends and patterns based on those findings.

The MMWR series is avilable online at:
http://www.cdc.gov/mmwr/publications/index.html

The CDC Surveillance Summaries are available online at:
http://www.cdc.gov/mmwr/mmwr_ss/ss_cvol.html

The Journal *Emerging Infectious Diseases*

This journal is published by the Centers for Disease Control and Prevention (CDC), and is ranked 3rd out of 57 infectious disease journals. *Emerging Infectious Diseases* receives more than 1,800 manuscripts each year (most unsolicited, some invited) from authors around the world. It has 17,000 subscribers to the print version in more than 100 countries and 33,000 subscribers to the electronic table of contents. The journal site receives hundreds of thousands of hits per month (CDC Web Statistics, http://www.cdc.gov/ncidod/EID/about/about.htm)

Emerging Infectious Diseases is available online at:
http://www.cdc.gov/ncidod/eid/index.htm

Public Health Image Library

The Centers for Disease Control and Prevention (CDC) created the Public Health Image Library (PHIL), recognizing that much of the information critical to the communication of public health messages is pictorial rather than text-based. The PHIL offers an organized, universal electronic gateway to CDC's pictures. Public health professionals, the media, laboratory scientists, educators, students, and the worldwide public are welcome to use this material for reference, teaching, presentation, and public health messages. The content is organized into hierarchical categories of people, places, and science, and is presented as single images, image sets, and multimedia files.

The PHIL is available online at:
http://phil.cdc.gov/phil/home.asp

The National Institutes of Health (NIH) Instruction in the Responsible Conduct of Research

The NIH requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant must receive instruction in responsible conduct of research. Responsible conduct of research is defined as the practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.

The NIH Policy is available online at:
http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html

NIH materials for Research Conduct and Ethics Instruction, including case studies for the 2010 theme (Science and Social Responsibility) are available online at:
http://sourcebook.od.nih.gov/resethicscases/2010-cases.pdf

The Center for Disease Control and Prevention (CDC) Clearance Policies

The Office of the Associate Director for Science (OADS) at the Center for Disease Control and Prevention (CDC) provides service and support to the CDC scientists as they work to protect people's health and improve the quality of their lives. OADS' focus is on strengthening the quality and integrity of CDC's science. Furthermore, by fostering innovative and successful scientific collaborations and partnerships OADS is also working towards enhancing the relevance of CDC's science and its health impact.

OADS' office is also a home to the Office of Science Quality and Translation (OSQT), which includes the Office of Extramural Research (OER) and is responsible for advancing the quality of CDC's science and championing the translation of research through the development of science policies and best practices (e.g., authorship, scientific clearance, peer review, and extramural research policies); and the Office of Scientific Integrity, which ensures that CDC science and research activities comply with various federal laws, regulations, and policies; coordinates the agency's 301(d) and 308(d) confidentiality protections; ensures leadership in public health ethics; and provides trainings to promote a well-educated and ethical domestic and international workforce at CDC.

Publication is encouraged and managed by editorial and clearance policies conducted at all levels of the Agency.

The clearance policy for information products disseminated outside CDC for public use is available online at:
http://www.cdc.gov/od/science/policies/clearance.htm

CDC Policy on oversight and clearance of dual use research of concern is available online at:
http://www.cdc.gov/OD/foia/policies/policy516.pdf

Form D

BWC - Confidence Building Measure

<u>Active Promotion of Contacts</u>

United States of America

April 15, 2011

Form D

Active promotion of contacts

1. Planned international conferences, symposia, seminars, and other similar forums for exchange

CDC and NIH Calendars
In addition to the specific conferences listed here, the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) host many other confrences, workshops and symposiums throughout the year. New events are always being added. Current listings of all CDC and NIH events are available online at:
http://www.cdc.gov/about/newsEvents/events.htm (CDC) and
http://calendar.nih.gov/app/MCalWelcome.aspx (NIH).

April 11-15, 2011
60th Annual Scientific Epidemic Intelligence Service (EIS) Conference
Atlanta, GA

The EIS hosts an annual scientific conference for the national and international public health community, where

- EIS officers' investigation findings are presented
- Current epidemiologic topics are discussed
- Epidemiologic activities at CDC are highlighted
- Public health professionals network and share ideas
- CDC programs recruit new EIS officers

For more information, please visit:
http://www.cdc.gov/eis/Conference.html

April 11-14, 2011
World Vaccine Congress (non-government)
Washington, D.C.

The World Vaccine Congress is a forum where the ever-changing dynamics of the industry are discussed and acted upon by the industry's most senior figures.

For more information, please visit:
http://www.terrapinn.com/conference/world-vaccine-congress-washington/index.stm

This conference is not being hosted by the US Government, but US Government researchers and grantees will likely participate.

May 16-18, 2011
14th Annual Conference on Vaccine Research (non-government)
Baltimore, MD

The annual Conference on Vaccine Research provides high quality, current reports of scientific progress featured in both invited presentations and submitted abstracts. The disparate fields covered in both human and veterinary vaccinology encourage valuable cross fertilization of ideas and approaches among researchers otherwise focused on specific diseases or methods. The Conference has become the largest scientific meeting devoted exclusively to research on vaccines and associated technologies for disease prevention through immunization. The latest vaccine-related scientific data, results, and issues are explored via symposia and panel discussions by expert faculty and through oral and poster sessions.

For more information, please visit:
http://www.nfid.org/conferences/vaccine11/

This conference is not being hosted by the U.S. Government, but U.S. Government researchers and grantees will likely participate.

May 16-18, 2011
Effective Risk Communication: Theory, Tools, and Practical Skills for Communicating about Risk (non-government)
Boston, MA

Most risk issues involve two hazards: the physical hazard itself, and the public reaction to it. Making wise choices requires understanding the risks and benefits of our technology and society. Risk communication is a tool for creating that understanding, closing the gap between laypeople and experts, and helping everyone make more informed choices. This introductory program will explore the scientific foundations for effective risk communication. This program is presented by prominent faculty from the Harvard School of Public Health, Harvard's Kennedy School of Government, the Risk Management Centre at King's College London, and the Center for Risk Perception and Communication at Carnegie Mellon University, and features the latest scientific findings on risk perception, case studies from around the world, a suite of practical tools, and hands-on skill training.

For more information, please visit:
https://ccpe.sph.harvard.edu/programs.cfm?CSID=RCC0000&pg=cluster&CLID=1

This conference is not being hosted by the U.S. Government, but U.S. Government researchers and grantees will likely participate.

May 17-20, 2011

Countering Biological Threats: National Implementation of the Biological Weapons Convention and Multinational Outbreak Response and Bioterrorism Investigation Demonstration

Tbilisi, Georgia

The U.S. Department of Defense and the U.S. Department of Health and Human Services will hold a conference and functional exercize in Tbilisi, Georgia, for civilian and military public health, law enforcement, military, and affiliated professionals from 10 countries as well as representatives of inter-governmental organizations (WHO, INTERPOL, NATO, UN Office of Disarmament Affairs (UNODA), and the Biological Weapons Convention (BWC) Implementation Support Unit).

The conference and functional exercise will build off the two multi-national workshops with associated tabletop exercises organized in 2010 in Georgia and Moldova by the U.S. Department of Defense and the U.S. Department of Health and Human Services. They promoted:

- strengthening the collaboration and partnership between national and international public health, security, and law enforcement communities in response to a biological incident;
- the review (and follow up for improvement if necessary) of existing legal and regulatory infrastructure of national measures consistent with the obligations and requirements of BWC, UNSCR 1540, and WHO IHR (2005) to deter, prevent, and respond to biological incidents or threats;
- enhanced awareness at the regional level of the potential nexus between criminal terrorist activities and cross-border proliferation of BW materials, in particular in the regions neighboring "frozen conflicts;" and
- linking the regional and global response to a bioterrorism incident stemming from the convergence of criminal and terrorist networks, with prevention via international nonproliferation mechanisms.

May 21-24, 2011

111th General Meeting of the American Society for Microbiology (non-government)

New Orleans, LA

Attendees will participate in intellectual sessions designed to inspire the connections and advancements critical to the future of microbiology. The speakers were selected as the best in their field by a newly organized planning committee. The daily schedule gives a chance to delve into both interdisciplinary subjects and specific disciplinary research. Complementing the scientific sessions will be outstanding student posters and an active Exhibit Hall.

For more information, please visit:
http://gm.asm.org/

This conference is not being hosted by the U.S. Government, but U.S. Government researchers and grantees will likely participate.

June 12-17, 2011
Gordon Research Conference on Mycotoxins and Phycotoxins (non-government)
Waterville, ME

This conference offers a unique international forum for academic, governmental and industrial scientists to exchange ideas, identify new research opportunities and initiate cross-disciplinary collaborations. Contemporary themes will be explored to facilitate the discussion of the "what, how, who, when, and why" of natural toxin events. Themes will include: 1) novel toxins and toxicities, 2) molecular mechanisms of toxicity and detoxification, 3) public health effects/disease epidemiology, 4) societal and economic impacts, 5) genetic and environmental control of toxigenesis, 6) physiological and ecological roles of toxins, 7) detection and predictive modeling, and 8) risk assessment and abatement.

For more information, please visit:
http://www.grc.org/programs.aspx?year=2011&program=mycotoxins

This conference is not being hosted by the U.S. Government, but U.S. Government researchers and grantees will likely participate.

June 20-23, 2011
Aerobiology in Biodefense IV Conference (non-government)
Virginia

Aerobiology in Biodefense is crucial to the Nation's goal to develop and license medical countermeasures to protect against aerosol biological threats. Aerobiology in Biodefense IV, to be held 20 - 23 June 2011 at Virginia Crossings, Richmond, Virginia, will allow a continuation of dialogue between the nation's bioaerosol research community. Topics include aerosol facilities, bioaccountability and biosecurity, aerosol science and technology, aerosol system design, bioaerosol characterization, standardization of aerosol systems, requirements for validation of aerosol systems, limitations of doing GLP studies in BSL-3 and 4 and FDA expectations, animal models, product efficacy studies, and aerosol drug delivery.

In addition, pre-conference workshops will be held. A basic workshop will introduce individuals new to the field to the essential elements of aerosol studies and discuss aerosol characterization, sampling and dosimetry. An advanced workshop will delve into dose calibration with focus on exposure chamber design, particle sizing, sampling, and aerosol deposition.

For more information, please visit:
https://www01.hjf.org/apps/internet/events2.nsf/eventView2/4FF523828FE618D3852577DD007703D8

June 27-30, 2011
Biotechnology Industry Organization (BIO) International Convention (non-government)
Washington, D.C.

The BIO International Convention is the world's largest gathering of thought leaders and decision makers in biotechnology. The event brings together 15,000 - 17,000 industry experts from 60 countries to share ideas, experiences, insights and best practices on biotech innovations that are helping to solve some of the biggest global challenges, including fighting disease and improving health, feeding growing populations and meeting the increased world demand for energy. BIO offers countless opportunities to learn, connect, and discover how to break through to success.

For more information, please visit:
http://convention.bio.org/

Within the BIO International Convention, there will be a Biosecurity Conference. This event will feature:

- Exposure to a full range of biotechnology and biosecurity professionals from industry, government, and the research community
- Wednesday Biosecurity Conference Keynote Address: Discussion of global biosecurity trends featuring a key thought-leader
- Seven Biosecurity Sessions on key issues impacting global biosecurity

For more information, please visit:
http://convention.bio.org/biosecurity

This conference is not being hosted by the U.S. Government, but U.S. Government researchers and grantees will likely participate.

July 16-20, 2011
30th Annual Meeting of the American Society for Virology (non-government)
Minneapolis, MN

The American Society for Virology (ASV) was founded in 1981 to provide a forum for investigators of human, animal, insect, plant, fungal and bacterial viruses, whether the research involves the use of clinical, ecological, biological or biochemical approaches. The Society sponsors an annual meeting, designed to promote discussion and collaboration among scientists active in all aspects of virology.

For more information, please visit:
http://www.cce.umn.edu/American-Society-for-Virology-Meeting/

This conference is not being hosted by the U.S. Government, but U.S. Government researchers and grantees will likely participate.

July 31-August 3, 2011

International Association for Food Protection (IAFP) Annual Meeting (non-government)

Milwaukee, WI

This Annual Meeting draws an international audience of food safety professionals. Educational sessions are dedicated to timely coverage of key issues and cater to multiple experience levels. The Annual Meeting has become the leading meeting concerned with the protection of the worldwide food supply. Each meeting is attended by over 2,000 of the top industry, academic and government food safety professionals. This broad mix of attendees includes professionals in quality control, processing operations, regulatory inspections, consulting groups, risk assessment, research and development, microbiological research, plant management, technical services and HACCP management. The Annual Meeting features over 500 technical papers, posters and symposia, which detail current information on a variety of topics relating to food safety. The quantity and quality of contributed presentations provide information on the latest methods and technologies available. The Annual Meeting exhibits are designed to be educational in nature, complementing the scientific content of the educational sessions. The Association emphasizes this by providing exhibitors and attendees a personalized setting where they can interact on a one-on-one basis. The exhibit portion of the Annual Meeting provides attendees the opportunity to gain "hands-on" knowledge of available technologies.

For more information, please visit:
http://www.foodprotection.org/events/iafp-annual-meeting/

This conference is not being hosted by the U.S. Government, but U.S. Government researchers and grantees will likely participate.

October 2-5, 2011

7th International Conference on Basic and Therapeutic Aspects of Botulinum and Tetanus Toxins (non-government)

Santa Fe, NM

This conference will feature a program consisting of internationally known basic and clinical scientists who will speak on the latest understandings of the basic biology of the neurotoxins and the science underlying their clinical applications. The Toxins 2011 meeting will be immediately followed by the 48th Annual Interagency Botulism Research Coordinating Committee - IBRCC Meeting scheduled to be held in Santa Fe, New Mexico, U.S. from October 6 - 7, 2011 which will focus on clinical botulism, epidemiology, and therapeutic interventions for botulism including vaccines, antitoxins and small molecule therapeutics. The organizers have developed programs for the two meetings with minimal overlap and encourage attendees to participate in both meetings.

For more information on both meetings, please visit:
http://www.cvent.com/EVENTS/Info/Summary.aspx?e=1f9662b7-a6eb-43fc-a8b6-c8b5347ba68d

This conference is not being hosted by the U.S. Government, but U.S. Government researchers and grantees will likely participate.

October 27-November 2, 2011
54th Annual Biological Safety Conference (non-government)
Anaheim, CA

The 54th Annual Biological Safety Conferences is sponsored by the American Biological Safety Association (ABSA). The 2011 Conference will feature:

- Four Full Days of Intensive Pre-Conference Courses
- Three Full Days of State of the Art Keynotes, Papers, and Panels
- Exhibits Showcasing the Latest in Laboratory Biosafety Products and Services
- Invaluable Networking with Biosafety Professionals

For more information, please visit:
http://www.absaconference.org/

This conference is not being hosted by the U.S. Government, but U.S. Government researchers and grantees will likely participate.

February 26-29, 2012
10th ASM Biodefense and Emerging Diseases Research Meeting (non-government)
Washington D.C.

Organizations around the world are involved in research pertaining to biothreat agents, vaccines, detection and diagnostic procedures, animal and plant pathogens, biosecurity facilities, global surveillance, the training of individuals in BSL-3 and BSL-4 labs, and other vital topics. As technology changes and research evolves, professionals involved in biodefense are being challenged to move ever faster to respond to the growing threat of bioterrorism. The ASM Biodefense and Emerging Diseases Research Meeting offers an educational forum which allows the attendee to:

- Discuss new data from the research of microbiological sciences related to biodefense and bioterrorism;
- Discuss with fellow scientists, researchers, and physicians, the latest information on preventative modalities, therapeutics, and clinical diagnoses related to biothreat agents; and
- Describe the most recent trends in the management and planning of biodefense programs.

The ASM Biodefense and Emerging Diseases Research Meeting is intended for scientists, physicians, public health researchers and policy makers who need to be informed about the latest scientific developments.

For more information, please visit:
http://www.asmbiodefense.org/

Form D

Active promotion of contacts

2. Information regarding other opportunities

Dual Use Concerns in Life Sciences Research
The National Institutes of Health (NIH) released a new educational video in June 2010 on the topic of dual use research in the life sciences. The video was developed to promote awareness and understanding about the dual use research issue by offering a conceptual overview through interviews with nationally respected scientists, institutional leaders, journal editors, and a member of the public. Discussants describe the need to ensure scientific progress while attending to scientific responsibility and important oversight and security concerns. The video is available on the Dual Use Program page of the Web site of the NIH Office of Biotechnology Activities (OBA, http://oba.od.nih.gov/biosecurity/biosecurity.html), as well as YouTube (http://www.youtube.com/watch?v=0yS1ur24j40). In addition, a hard copy of the video was made available in November 2010; up to five copies of the DVD are available free-of-charge, and may be requested by writing to OBA and providing your full mailing address.

Planned National Science Advisory Board for Biosecurity (NSABB) Meetings
The purpose of the National Science Advisory Board for Biosecurity (NSABB) is to provide advice, guidance, and leadership regarding biosecurity oversight of dual use research, defined as biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security. The NSABB will provide advice on and recommend specific strategies for the efficient and effective oversight of federally conducted or supported dual use biological research, taking into consideration both national security concerns and the needs of the research community to foster continued rapid progress in public health and agricultural research. Toward this end, the NSABB will also include providing strategies to raise awareness if dual use issues relevant to the life science and related interdisciplinary research communities.

NSABB meetings are planned for: February 8-10, 2011, June 21-23, 2011 and October 25-27, 2011.

For more information, please visit:
http://oba.od.nih.gov/biosecurity/biosecurity_meetings.html

International Training and Career Opportunities available via the National Institutes of Health (NIH) John E. Fogarty International Center for Advanced Study in the Health Sciences
The Fogarty International Center is the international component of the NIH. It addresses global health challenges through innovative and collaborative research and training programs and supports and advances the NIH mission through international partnerships. Fogarty's Research Training Grants provide funding to train researchers, building sustainable research capacity in

low- and middle-income countries. Grants are available in a variety of research areas, such as infectious diseases, chronic conditions, population health, informatics, genetics, and clinical, operational and health services. The Division of International Training and Research (DITR) administers research grants, training grants and fellowship programs which are active in over 100 countries (website: http://www.fic.nih.gov/about/ditr.htm).

A comprehensive list of Research Training Grant programs is available online at: http://www.fic.nih.gov/programs/training_grants/index.htm

The FDA's NCTR International Scientist Exchange Program

The National Center for Toxicological Research (NCTR) is an FDA research center that provides global leadership and innovative scientific solutions in support of FDA's mission to improve public health. In cooperation with FDA's Office of International Programs, NCTR has established an International Scientist Exchange Program (ISEP) to provide scientific training to students, regulators and academicians from developing countries. NCTR has a long history of providing scientific training to research scientists, including international scientists. In 2009, NCTR expanded its training of international scientists to focus on capacity building by establishing ISEP. This program focuses the NCTR training experience on learning concepts, skills and techniques that are critical for scientists to build the scientific infrastructure needed to be successful in the global context.

More information is available online at: http://www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/ucm224160.htm

Food and Drug Administration (FDA) International Programs-Communications

The overall purpose of the U.S. FDA's Office of International Programs (OIP) communications internationally is to effectively communicate FDA policy, regulatory decisions, and programs to counterpart government officials and international organizations around the world, to enhance cooperation with them on public health matters of mutual interest, and provide prompt, accurate, and effective responses to a wide range of requests for program, policy, and technical information. OIP coordinates, organizes and conducts major international conferences, symposia, workshops, and embassy briefings in areas of specific Agency concern, including annual meetings with counterpart agencies. OIP serves as the agency focal point on policies and procedures for sharing public and non-public information. In this regard, OIP is the primary agency liaison with other U.S. Government components, international and foreign governments (including Washington, D.C. embassies) in disseminating public and non-public information concerning international notifications of recalls in the United States of products that have been distributed abroad. As FDA becomes aware of distribution outside the U.S. of products recalled domestically, the FDA/OIP immediately provides information by e-mail to international regulatory counterparts about these products. These notifications are made directly to the senior executives of our counterpart food and medical product safety agencies, to technical counterparts, and/or to the embassy of the country involved.

For more information, please visit:
http://www.fda.gov/InternationalPrograms/InternationalCommunications/default.htm

Food and Drug Administration (FDA) International Programs-Capacity Building
The FDA's technical cooperation and capacity-building efforts are related to the development, utilization, and enforcement of international scientific regulatory standards that help assure globally the efficacy, safety, wholesomeness, and quality of FDA-regulated products.

Given the accelerating challenges of a globalized supply chain, the U.S. FDA collaborates with regulatory counterparts of other countries, multi-lateral organizations, other U.S. Government agencies and global initiatives to improve regulatory infrastructures, preventive controls and production practices.

In support of global harmonization efforts, technical cooperation and capacity building activities include sharing information about applicable regulatory disciplines and import requirements; assisting with strengthening detection, surveillance and assessment systems; and designing and developing data/information systems and platforms. These efforts are provided through numerous modalities, including cooperative agreements with multilateral agencies; in-class and train-the trainers programs; web-based modules; publications; and other multi-media materials.

In 2010, the following Cooperative Agreements were developed by the FDA:

- Cooperative Agreement To Support Capacity Building Activities Through the World Health Organization Global Foodborne Infections Network (http://edocket.access.gpo.gov/2010/2010-24903.htm)
- Cooperative Agreement With the Pan American Health Organization for the Development of an Information Hub for Medical Products and Related Regulatory Processes and Systems in the Americas Region (http://edocket.access.gpo.gov/2010/2010-24906.htm)
- Cooperative Agreement With the World Health Organization for a Plan to Develop a Global Integrated Food Safety Information Platform (http://edocket.access.gpo.gov/2010/2010-24904.htm)

For more information, please visit:
http://www.fda.gov/InternationalPrograms/CapacityBuilding/default.htm

Food and Drug Administration (FDA) International Programs-Geographic Programs
Globalization is a fact of 21st century economic life. It has resulted in United States markets being composed of a myriad of imported goods that our consumers want and need. Based on the volume of imported products from specific areas, problems that have been associated with products over the years, and the value to be derived from leveraging the activities and resources of trusted foreign counterpart regulatory authorities, FDA has established a permanent presence in China, India, Europe, and Latin America. Other locations are being considered. More

information is available online at:
http://www.fda.gov/InternationalPrograms/FDABeyondOurBordersForeignOffices/default.htm

Centers for Disease Control and Prevention (CDC) Training and Educational Materials
Emergency Preparedness and Response: The CDC provides resources that are intended to help professionals take an all-hazards approach to preparedness. These materials are available online at: http://emergency.cdc.gov/hazards-all.asp.
A list of training resources related specifically to bioterrorism is available online at:
http://emergency.cdc.gov/bioterrorism/training.asp

International Laboratory-related Resource and Activity Directory: This directory includes links to training materials, guidelines, manuals, and resources developed by CDC and partner organizations to promote quality laboratory practices in the global laboratory setting. These resources are available online at: http://wwwn.cdc.gov/dls/ILA/default.aspx

The Public Health Training Network (PHTN): This is a distance learning network of people and resources that takes training and information to the learner. A listing of distance learning courses and resources is available online at: http://www2.cdc.gov/PHTN/calendar.asp

Training and Continuing Education Online (TCEO): TCEO is a distance learning network that allows participants to register for CDC-managed courses and track their progress online. TCEO is available online at:http://www2a.cdc.gov/TCEOnline/index.asp

Other learning resources are available online at the CDC Learning Connection Website (http://www.cdc.gov/learning/index.html). This is a newly established website, designed to help visitors locate public health learning products created by CDC and partners. It features a growing collection of free products in various media formats, including podcasts, e-learning, electronic publications, and live events.

Events organized by the U.S. Government in Georgia and the Republic of Moldova
In 2010 the Department of Health and Human Services (HHS) and the Department of Defense organized The Southern Caucasus Workshop on Public Health, Security, and Law Enforcement Partnership in Bio-Incident Pre-Planning and Response and the associated Southern Caucasus BioShield 2010 Tabletop Exercise in Tbilisi, Georgia, 11-12 May 2010, as well as the Trilateral (US-Romania-Moldova) Civilian-Military Forum on Outbreak Response and Bioterrorism Investigation (ORBIT Forum) in Chisinau, Republic of Moldova October 19-21, 2010. More information is available online at:
http://www.phe.gov/Preparedness/international/Pages/southerncaucasus.aspx and
http://www.phe.gov/Preparedness/international/Pages/orbitforum.aspx

There were about 80 participants were in attendance at the Southern Caucasus Worshop and Tabletop Exercise, from inter-governmental organizations (WHO, INTERPOL, NATO), US Government, and from public health, security, or law enforcement organizations from Georgia, Azerbaijan, Armenia, Kazakhstan, Moldova, and Romania. Non-governmental organizations

such as VERTIC (Verification Research, Training and Information Centre), Bechtel, and Global Green USA were also represented at the workshop.

The workshop and tabletop exercise aimed to:

- Foster improved understanding of the respective procedures and requirements of public health, security, and law enforcement communities in response to a biological incident, and enhance their joint effectiveness in pre-planning and response at the national and regional/international level;
- Enhance understanding of intergovernmental organizations' role and their interaction in the process of sharing information and coordinating the international response;
- Emphasize the concept that information exchange in the early stages of a biological incident is critical to effectively containing the outbreak/mitigating the consequences of a biological incident and to apprehending the potential perpetrators;
- Review existing legal and regulatory infrastructure of national measures consistent with the obligations under the Biological Weapons Convention (BWC), UN Security Council Resolution 1540 (UNSCR 1540), and WHO International Health Regulations (IHRs) to deter, prevent, or respond to biological incidents or threats.

An after action report is available online at:
http://www.phe.gov/Preparedness/international/Documents/southerncaucasusworkshop.pdf

The ORBIT Forum was attended by about 100 participants including civilian and military public health personnel, law enforcement, intelligence, military, and affiliated professionals, and representatives of non-governmental organizations from US, Romania, and Moldova. Also in attendance were representatives of inter-governmental organizations (WHO, European Centre for Disease Control and Prevention, Interpol, NATO, UN Office of Disarmament Affairs, and the Biological Weapons Convention Implementation Support Unit).

The goals of this event were to:

- promote interagency (in particular public health-law enforcement but also civilian-military) cooperation, coordination and synchronization for preparing, detecting, and responding to infectious disease outbreaks, whether natural, accidental, or deliberate in nature
- establish sustainable laboratory partnerships to enhance training and medical surveillance initiatives among the three countries
- strengthen the core capacities required by the WHO International Health Regulations and existing national measures consistent with obligations under the Biological Weapons Convention and the UN Security Council Resolution 1540 to deter, prevent, and respond to biological incidents or threats.

An after action report is available online at:
http://www.phe.gov/Preparedness/international/Documents/orbit-after-action.pdf

The National Science Advisory Board for Biosecurity (NSABB) International Working Group

The NSABB International Working Group aims to develop and support the implementation of strategies to foster international engagement on issues related to dual use life sciences research.

On September 22, 2010, the NSABB International Working group partnered with the European Molecular Biology Organization, the European Science Foundation, Institut Pasteur, and the European Society of Clinical Microbiology and Infectious Diseases to produce an interactive international webcast, entitled "Does Your Research Raise Security Concerns?" The archived webcast is available online at:
http://oba.od.nih.gov/biosecurity/internationalwebcast_europe2010.html

On November 1, 2010, the NSABB hosted a videoteleconference sponsored by the US National Institutes of Health (NIH) and the Chinese Academy of Sciences (CAS). This videoteleconference engaged attendees in a session of the Trends in Science and Technology Relevant to the Biological and Toxin Weapons Convention Workshop held in Beijing, China.

For more information on both of these events, please visit:
http://oba.od.nih.gov/oba/biosecurity/meetings/Oct2010/International_Working_Group_Slides.pdf

The FDA's Food Defense and Emergency Response-Training

FDA works with other government agencies and private sector organizations to help reduce the risk of tampering or other malicious, criminal, or terrorist actions on the food and cosmetic supply. Web-based training resources and additional educational resources are available online at: http://www.fda.gov/Food/FoodDefense/default.htm

Synthetic Biology Program

To address the potential misuse of technological advances that enable the synthetic generation of DNA sequences, the FBI has partnered with HHS, USDA, DOS, Department of Commerce (DOC), DHS, and the synthetic DNA industry to develop a mechanism to report, respond to, and investigate suspicious purchase requests of potentially harmful DNA sequences. Working with industry, procedures have been developed to screen unusual purchases, including those that may involve sequences associated with Select Agents, to create a reporting mechanism for suspicious orders that may pose a threat.

Biological Sciences Outreach Program

This initiative seeks to develop a partnership and a dialogue between the FBI and the research community to establish norms for the reporting of suspicious incidents. Through this initiative, the FBI educates partners on security issues and the "real world" threat and serves as a resource for risk mitigation. The research community benefits by increasing its capacity to self-regulate and self-police. The FBI, in turn, benefits by gaining subject matter expertise on emerging threats and increased reporting of suspicious events.

The FBI has worked with the Federation of American Scientists (FAS); the American Association for the Advancement of Science (AAAS); and the National Institutes of Health (NIH), Office of Biotechnology Activities (OBA), to develop educational and training materials on biosecurity. These materials are provided during outreach events to the biological sciences communities to help foster the development of a culture of responsibility.

Form E

BWC - Confidence Building Measure

Declaration of Legislation, Regulations, and other Measures

United States of America

April 15, 2011

Form E

Declaration of legislature, regulations and other measures relating to

	Legislation	Regulations	Other	Amended Since Last year
Development, production, stockpiling, acquisition or retention of microbial or other biological agents, or toxins, weapons, equipment and means of delivery specified in Article I	YES	YES	YES	YES
Import of Micro-Organisms and Toxins.	YES	YES	YES	NO
Export of Micro-Organisms and Toxins.	YES	YES	NO	YES

On December 20, 2010, HHS published its semiannual regulatory agenda outlining the Obama Administration's planned regulatory initiatives in a number of health policy areas: (http://edocket.access.gpo.gov/2010/pdf/2010-30444.pdf). The information provided in the Agenda presents a forecast of the rulemaking activities that the Department of Health and Human Services (HHS) expects to undertake in the foreseeable future. Rulemakings are grouped according to pre-rulemaking actions, proposed rules, final rules, long-term actions, and rulemaking actions completed since the Spring 2009 Agenda was published.

Export Administration Regulations - Regulation Change
A regulation change was published in the March 23, 2010 Federal Register (75 FR 13672) (www.access.gpo.gov/bis/fedreg/ear_fedreg10.html#14335) to amend the Export Administration Regulations by removing "white pox" virus (Export Control Classification Number ECCN 1C351, human and zoonotic pathogens and "toxins") from the Commerce Control List of biological agents.

Final Rule Stage: Control of Communicable Diseases: Foreign and Possessions
Action: Final Action 12/00/10

By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Communicable disease regulations are divided into two parts: Part 71 pertaining to foreign arrivals and part 70 pertaining to interstate matters. This rule (42 CFR Part 71) will update and improve CDC's response to both global and domestic disease threats by creating a multi-tiered illness detection and response process thus substantially enhancing the public health system's ability to slow the introduction, transmission, and spread of communicable disease. The final rule focuses primarily on

requirements relating to the reporting of deaths and illnesses onboard aircrafts and ships, and the collection of specific traveler contact information for the purpose of CDC contacting travelers in the event of an exposure to a communicable disease.

Final Rule Stage: Possession, Use, and Transfer of Select Agents and Toxins: Chapare Virus (Chapter 610 Review)
Action: Final Action 11/00/11

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorizes the HHS Secretary to regulate the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. These regulations are set forth at 42 CFR 73. Criteria used to determine whether a select agent or toxin should be included under the provisions of these regulations are based on: (1) The effect on human health as a result of exposure to the agent or toxin, (2) the degree of contagiousness of the agent or toxin, (3) the methods by which the agent or toxin is transferred to humans, (4) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent and illness resulting from infection by the agent or toxin, and (5) any other criteria, including the needs of children and other vulnerable populations that the HHS Secretary considers appropriate. Based on these criteria, we are proposing to amend the list of HHS select agents and toxins by adding Chapare virus to the list. After consulting with subject matter experts from CDC, the National Institutes of Health (NIH), the Food Drug Administration (FDA), the United States Department of Agriculture (USDA) /Animal and Plant Health Inspection Service (APHIS), USDA/Agricultural Research Service (ARS), USDA/CVB (Center for Veterinary Biologics), and the Department of Defense (DOD)/United States Army Medical Research Institute for Infectious Diseases (USAMRIID) and review of relevant published studies, we believe the Chapare virus should be added to the list of HHS select agents and toxins based on our conclusion that the Chapare virus has been phylogenetically identified as a Clade B arenavirus and is closely related to other South American arenaviruses that cause haemorrhagic fever, particularly Sabia virus.

Other Measures: Executive Order 13539 of April 21, 2010: President's Council of Advisors on Science and Technology (PCAST)
The PCAST shall advise the President, directly at its meetings with the President and also through the Science Advisor, on matters involving science, technology, and innovation policy. This advice shall include, but not be limited to, policy that affects science, technology, and innovation, as well as scientific and technical information that is needed to inform public policy relating to the economy, energy, environment, public health, national and homeland security, and other topics.

The full text of this Executive order is available online at:
http://edocket.access.gpo.gov/2010/pdf/2010-9796.pdf

Other Measures: Executive Order 13546 of July 2, 2010: Optimizing the Security of Biological Select Agents and Toxins (BSAT) in the United States

To help ensure that BSAT are secured according to level of risk, the Secretaries of Health and Human Services and Agriculture shall, through their ongoing review of the biological Select Agents and Toxins List (Select Agent List) contained in regulations, and no later than 18 months from the date of this order:

- designate a subset of the Select Agent List (Tier 1) that presents the greatest risk of deliberate misuse with most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence;
- explore options for graded protection of Tier 1 agents and toxins as described in subsection (a) of this section to permit tailored risk management practices based upon relevant contextual factors; and
- consider reducing the overall number of agents and toxins on the Select Agent List.

To ensure that the policies and practices used to secure BSAT are harmonized and that the related oversight activities of the Federal Government are coordinated, the heads of executive departments and agencies identified in section 7(a)(ii) of this order shall:

- no later than 6 months from the date of this order, develop and implement a plan for the coordination of BSAT security oversight that: (i) articulates a mechanism for coordinated and reciprocal inspection of and harmonized administrative practices for facilities registered with the SAP; (ii) ensures consistent and timely identification and resolution of BSAT security and compliance issues; (iii) facilitates information sharing among departments and agencies regarding ongoing oversight and inspection activities; and (iv) provides for comprehensive and effective Federal oversight of BSAT security; and
- no later than 6 months from the issuance of final rules and guidance as described in section 5 of this order, and annually thereafter, review for inconsistent requirements and revise or rescind, as appropriate, any regulations, directives, guidance, or policies regarding BSAT security within their department or agency that exceed those in the updated SAR and guidance as described in section 5 of this order.

The full text of this Executive order is available online at:
http://edocket.access.gpo.gov/2010/pdf/2010-16864.pdf

DOJ/FBI Process and Criteria for Sharing Select Agent Program Information

Pursuant to Section 8 (Sharing of Select Agent Program Information) of Executive Order 13546 (Optimizing the Security of Biological Select Agent and Toxins), the FBI developed a document which describes the process and criteria by which the U.S. Department of Justice (DOJ) and/or the Federal Bureau of Investigation (FBI) will share Select Agent Program information with executive departments and agencies when such information is necessary for furthering a public health, safety, security, law enforcement, or national security mission.

Other Measures: Health and Human Services (HHS) Secretary's Strategic Initiatives & Key Inter-Agency Collaborations

Improve Global Health: HHS has significant scientific, technical, and regulatory expertise in global health matters. HHS's experience helps ensure that activities are informed by research, disease surveillance, public health service delivery, medical product and food safety, and best practices to strengthen health systems.HHS is collaborating with its partners and the White House on several issues in global health, including advancing global pandemic preparedness and response, combating bio-terrorism, and implementing the President's Global Health Initiative.

HHS, through the CDC, NIH, FDA, HRSA, and other operating divisions, is pursuing the following actions to improve global health:

- Combating Infectious Diseases through Rapid Identification and Control Efforts
- Combating Non-Infectious Diseases through Strategic Partnerships
- Developing a Global Health Strategy

Foster Open Government: As detailed in its Open Government Plan, HHS will undertake bold actions to foster open government in the coming months, including the following:

- Leverage Data for Maximum Public Good
- Promote Best Practices through Public Participation and Collaboration
- Foster Innovation at HHS

The full text of the Secretary's Strategic Initiatives & Key Inter-Agency Collaborations is available online at: http://www.hhs.gov/secretary/about/secretarialstrategicinitiatives2010.pdf

Other Measures: National Security Strategy 2010

The National Security Strategy, released in May 2010 notes of biological threats that "The effective dissemination of a lethal biological agent within a population center would endanger the lives of hundreds of thousands of people and have unprecedented economic, societal, and political consequences. We must continue to work at home with first responders and health officials to reduce the risk associated with unintentional or deliberate outbreaks of infectious disease and to strengthen our resilience across the spectrum of high-consequence biological threats. We will work with domestic and international partners to protect against biological threats by promoting global health security and reinforcing norms of safe and responsible conduct; obtaining timely and accurate insight on current and emerging risks; taking reasonable steps to reduce the potential for exploitation; expanding our capability to prevent, attribute, and apprehend those who carry out attacks; communicating effectively with all stakeholders; and helping to transform the international dialogue on biological threats."

The full text of this strategy is available online at:
http://www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf

Other Measures: Screening Framework Guidance for Providers of Synthetic Double Stranded DNA

Synthetic biology is poised to become the next significant technology transforming the life sciences and other scientific fields. This developing interdisciplinary field focuses on the design and fabrication of novel biological components and systems, as well as on the re-design and fabrication of existing biological systems. To balance the promise of synthetic biology and the potential biosecurity risks, the U.S. government developed *Screening Framework Guidance for Providers of Synthetic Double-Stranded DNA*. The Department of Health and Human Services led a broad interagency effort to develop the document, which was released on Oct. 13, 2010. The document strives to minimize any negative impacts on the conduct of research and business operations while meeting national biosecurity goals.

Following this Guidance is voluntary, though many specific recommendations serve to remind providers of their obligations under existing regulations. Briefly, upon receiving an order for synthetic dsDNA, the U.S. Government recommends that providers perform customer screening and sequence screening. If either customer screening or sequence screening raises any concerns, providers should perform follow-up screening. If follow-up screening does not resolve concerns about the order or there is reason to believe a customer may intentionally or inadvertently violate U.S. laws, providers should contact designated entities within the U.S. Government for further information and assistance. This Guidance also provides recommendations regarding proper records retention protocols and screening software.

A copy of the report is available online at:
http://www.phe.gov/Preparedness/legal/guidance/syndna/Documents/syndna-guidance.pdf

Other Measures: The Ethics of Synthetic Biology and Emerging Technologies

The President asked the Presidential Commission for the Study of Bioethical Issues to recommend how the developing field of synthetic biology and related technologies can maximize public benefits, minimize risks, and observe appropriate ethical boundaries. In a report released in December 2010, the Commission recommended "that the government, through a coordinated process or body within the Executive Office of the President, lead an ongoing review of developments, risks, opportunities, and oversight as this field grows. This review should be in consultation with relevant scientific, academic, international, and public communities, and whenever possible its results should be made public. We also recommend that reasonable risk assessment should precede any field release of synthetic organisms. We suggest support for public engagement, education, and dialogue to ensure public trust and avoid unnecessary limitations on science and social progress."

The report is available online at: http://www.bioethics.gov/documents/synthetic-biology/PCSBI-Synthetic-Biology-Report-12-16-10.pdf

Proposed Rule Stage: Control of Communicable Diseases: Foreign and Possessions Regulations; Nonhuman Primate

Action: NPRM (Notice of Proposed Rulemaking) 01/00/11 (published 01/04/2011)

By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. The Secretary has delegated the authority to prevent the introduction of diseases from foreign countries to the Director, CDC. CDC also enforces entry requirements for certain animals, etiologic agents, and vectors deemed to be of public health significance. CDC is proposing to amend its regulations related to the importation of live nonhuman primates (NHPs) by extending existing requirements for the importation of cynomolgus, African green, and rhesus monkeys to all NHPs. The agency also is proposing to reduce the frequency at which importers of the three species are required to renew their registrations, (from every 180 days to every two years). CDC proposes to incorporate existing guidelines into the regulations and add new provisions to address NHPs imported as part of a circus or trained animal act, NHPs imported by zoological societies, the transfer of NHPs from approved laboratories, and non-live imported NHP products. CDC is also proposing that all NHPs be imported only through ports of entry where a CDC quarantine station is located.

Revision of Bioterrorism Security Risk Assessment Form

As required by the U.S. Public Health Security and Bioterrorism Preparedness Response Act of 2002, the FBI conducts national security risk assessments for entities and individuals that have access to select agents and toxins. In early 2011, the FBI plans to modify the Bioterrorism Security Risk Assessment Form to allow greater opportunity for relevant parties at the administrative level to review the applicant's answers and follow-up on any discrepancies. The modification will also serve as a reminder for research directors that the individual that they are sponsoring into the Select Agent Program must meet the standards set forth in the regulations. The modification will foster greater due diligence at the local level and will benefit the Select Agent Program by having more fully vetted applicants being forwarded to the FBI, which should lead to significantly fewer denial or follow-up actions.

Form F

BWC - Confidence Building Measure

Declaration of Past Activities in Offensive and/or Defensive Biological Research and Development Programmes

United States of America

April 15, 2011

Form F

Declaration of Past Activities in Offensive and/or Defensive Biological Research and Development Programmes

1. **Date of entry into force of the Convention for the State party.**

   3/26/1975

2. **Past offensive biological research and development programmes:**

   Nothing new to declare.

Form G

BWC - Confidence Building Measure

Declaration of Vaccine Production Facilities

United States of America

April 15, 2011

Form G

Declaration of Vaccine Production Facilities

The following website is provided by the US Food and Drug Administration as a reference for a current list of vaccines licensed in the United States and associated production facilities:

http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm093833.htm

Data provided in CBM Form G constitute excerpts from the information provided on the publicly available website listed above (as accessed on 25 February 2011). Trade names are included when provided by the manufacturer. Specific and current information about the vaccine and contact information for the manufacturer is available by following the hyperlinks provided on the above website.

Form G

Declaration of Vaccine Production Facilities

1. **Name of facility**

   Emergent BioDefense Operations Lansing, Inc.

2. **Location (Mailing Address)**

   3500 N. Martin Luther King Jr. Blvd.
   Lansing, Michigan 48906

3. **General description of the types of diseases covered:**

   Anthrax disease caused by *Bacillus anthracis*

   Vaccines:
   - Anthrax Vaccine Adsorbed - [BioThrax]

Form G

Declaration of Vaccine Production Facilities

1. **Name of facility**

   MassBiologics

2. **Location (Mailing Address)**

   University of Massachusetts Medical School
   Boston, Massachusetts 02130

3. **General description of the types of diseases covered:**

   Diphtheria and tetanus caused by Corynebacterium diphtheriae and Clostridium tetani.

   Vaccines:
   - Tetanus and Diphtheria Toxoids Adsorbed

Form G

Declaration of Vaccine Production Facilities

1. **Name of facility**

   MedImmune LLC

2. **Location (Mailing Address)**

   One MedImmune Way
   Gaithersburg, Maryland 20878

3. **General description of the types of diseases covered:**

   Influenza disease caused by pandemic (H1N1) 2009 virus. Influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

   Vaccines:
   - Influenza A (H1N1) 2009 Monovalent Vaccine
   - Influenza Vaccine Live, Intranasal - [FluMist]

Form G

Declaration of Vaccine Production Facilities

1. **Name of facility**

   Merck & Co, Inc (NJ)

2. **Location (Mailing Address)**

   One Merck Drive
   P.O. Box 100
   Whitehouse Station, New Jersey 08889-0100

3. **General description of the types of diseases covered:**

   Invasive disease caused by *Haemophilus influenzae* type b; infection caused by all known subtypes of hepatitis B virus; Hepatitis A disease; cervical, vulvar and vaginal cancer and certain other diseases caused by Human Papillomavirus (HPV) Types 6, 11, 16, and 18; Measles (rubeola); Mumps; diseases caused by *Streptococcus pneumoniae*; Rotavirus disease; Rubella (German measles) disease; Varicella disease caused by the varicella-zoster virus (VZV); Herpes zoster (shingles) disease.

   Vaccines:
   - Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) - [PedvaxHIB]
   - Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate) & Hepatitis B (Recombinant) Vaccine - [COMVAX]
   - Hepatitis A Vaccine, Inactivated - [VAQTA]
   - Hepatitis B Vaccine (Recombinant) - [Recombivax HB]
   - Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant - [Gardasil]
   - Measles, Mumps, and Rubella Virus Vaccine, Live - [M-M-R II]
   - Measles, Mumps, Rubella and Varicella Virus Vaccine Live - [ProQuad]
   - Pneumococcal Vaccine, Polyvalent - [Pneumovax 23]
   - Rotavirus Vaccine, Live, Oral, Pentavalent - [RotaTeq]
   - Varicella Virus Vaccine Live - [Varivax]
   - Zoster Vaccine, Live, (Oka/Merck) - [Zostavax]

Form G

Declaration of Vaccine Production Facilities

1. **Name of facility**

   Organon Teknika Corporation LLC

2. **Location (Mailing Address)**

   100 Rodolphe Street
   Building 1300
   Durham, North Carolina 27712

3. **General description of the types of diseases covered:**

   For the prevention of tuberculosis in persons not previously infected with M. tuberculosis who are at high risk for exposure; For the treatment and prophylaxis of carcinoma in situ (CIS) of the urinary bladder; For the prophylaxis of primary or recurrent state Ta and/or T1 papillary tumors following transurethral resection (TUR).

   Vaccines:
   - BCG Live vaccine - [BCG Vaccine; TICE BCG]

Form G

Declaration of Vaccine Production Facilities

1. **Name of facility**

   Sanofi Pasteur Biologics Co.

2. **Location (Mailing Address)**

   38 Sidney Street
   Cambridge, Massachusetts 02139

3. **General description of the types of diseases covered:**

   Smallpox disease

   Vaccines:
   - Smallpox (Vaccinia) Vaccine, Live - [ACAM2000]

Form G

Declaration of Vaccine Production Facilities

1. **Name of facility**

   Sanofi Pasteur, Inc

2. **Location (Mailing Address)**

   Discovery Drive
   Swiftwater, Pennsylvania 18370

3. **General description of the types of diseases covered:**

   Diphtheria caused by Corynebacterium diphtheria; tetanus caused by Clostridium tetani; pertussis diseases; influenza disease caused by pandemic (H1N1) 2009 virus; influenza disease caused by H5N1 subtype; influenza disease caused by influenza virus subtypes A and type B; invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, Y and W-135; meningitis and meningococcemia caused by N. meningitidis; and Yellow fever acute viral illness caused by a mosquito-borne flavivirus.

   Vaccines:
   - Diphtheria & Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed - [Tripedia; DTaP]
   - Diphtheria and Tetanus Toxoids Adsorbed
   - Influenza A (H1N1) 2009 Monovalent Vaccine
   - Influenza Virus Vaccine, H5N1 (for National Stockpile)
   - Influenza Virus Vaccine, Trivalent, Types A and B33 - [Fluzone® and Fluzone High-Dose]
   - Meningococcal Polysaccharide (Serogroups A, C, Y and W-135) Diphtheria Toxoid Conjugate Vaccine - [Menactra®]
   - Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined - [Menomune®-A/C/Y/W-1351]
   - Tetanus and Diphtheria Toxoids Adsorbed
   - Tetanus and Diphtheria Toxoids Adsorbed for Adult Use - [DECAVAC]
   - Tetanus Toxoid Adsorbed
   - Tetanus Toxoid for Booster Use Only
   - Yellow Fever Vaccine - [YF-VAX®]

Form G

Declaration of Vaccine Production Facilities

1. **Name of facility**

   Wyeth Pharmaceuticals Inc

2. **Location (Mailing Address)**

   Pfizer, Inc.,
   235 East 42nd Street
   New York, New York 10017

3. **General description of the types of diseases covered:**

   Invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F and otitis media caused by Streptococcus pneumoniae serotypes 4, 6B, 9V, 14, 18C, 19F and 23F.

   Vaccines:
   - Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein) - [Prevnar 13™]
   - Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM197 Protein) - [Prevnar®]

Appendix A

Biological Select Agents and Toxins

Biological Select Agents and Toxins are biological pathogens and toxins that the United States has determined have the potential to pose a severe threat to public health and safety, animal and plant health, or animal and plant products. The possession, use, and transfer of these agents is regulated by the U.S. Department of Health and Human Services (HHS) Centers for Disease Control and Prevention and the U.S. Department of Agriculture Animal and Plant Health Inspection Service under the Select Agent Regulations found in Part 73 of Title 42 of the Code of Federal Regulations, Part 331 of Title 7 of the Code of Federal Regulations, and Part 121 of Title 9 of the Code of Federal Regulations.

Information on Biological Select Agents and Toxins can be found on the National Select Agent Registry website: http://www.selectagents.gov/

HHS Select Agents and Toxins

Abrin
Botulinum neurotoxins
Botulinum neurotoxin producing species of *Clostridium*
Cercopithecine herpesvirus 1 (Herpes B virus)
Clostridium perfringens epsilon toxin
Coccidioides posadasii/Coccidioides immitis
Conotoxins
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus
Ebola virus
Francisella tularensis
Lassa fever virus
Marburg virus
Monkeypox virus
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed1918 Influenza virus)
Ricin
Rickettsia prowazekii
Rickettsia rickettsii
Saxitoxin
Shiga-like ribosome inactivating proteins
Shigatoxin
South American Haemorrhagic Fever viruses
- Flexal
- Guanarito
- Junin
- Machupo
- Sabia

Staphylococcal enterotoxins
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses
- Central European Tick-borne encephalitis
- Far Eastern Tick-borne encephalitis
- Kyasanur Forest disease
- Omsk Hemorrhagic Fever
- Russian Spring and Summer encephalitis

Variola major virus (Smallpox virus)
Variola minor virus (Alastrim)
Yersinia pestis

OVERLAP Select Agents and Toxins

Bacillus anthracis
Brucella abortus
Brucella melitensis
Brucella suis
Burkholderia mallei (formerly *Pseudomonas mallei*)
Burkholderia pseudomallei (formerly *Pseudomonas pseudomallei*)
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan Equine Encephalitis virus

USDA Select Agents and Toxins

African horse sickness virus
African swine fever virus
Akabane virus
Avian influenza virus (highly pathogenic)
Bluetongue virus (exotic)
Bovine spongiform encephalopathy agent
Camel pox virus
Classical swine fever virus
Ehrlichia ruminantium (Heartwater)
Foot-and-mouth disease virus
Goat pox virus
Japanese encephalitis virus
Lumpy skin disease virus
Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1)
Menangle virus
Mycoplasma capricolum subspecies *capripneumoniae* (contagious caprine pleuropneumonia)
*Mycoplasma mycoid*es subspecies mycoides small colony (*Mmm* SC) (contagious bovine pleuropneumonia)
Peste des petits ruminants virus
Rinderpest virus
Sheep pox virus
Swine vesicular disease virus
Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3
Virulent Newcastle disease virus 1

USDA PLANT PROTECTION AND QUARANTINE (PPQ) Select Agents and Toxins

Peronosclerospora philippinensis (*Peronosclerospora sacchari*)
Phoma glycinicola (formerly Pyrenochaeta glycines)
Ralstonia solanacearum race 3, biovar 2
Rathayibacter toxicus
Sclerophthora rayssiae var zeae
Synchytrium endobioticum
Xanthomonas oryzae
Xylella fastidiosa (citrus variegated chlorosis strain)

Appendix A

NIAID Category A, B, and C Priority Pathogens
The National Institute of Allergy and Infectious Disease (NIAID) categorization of pathogens identifies specific pathogens as priorities for additional research efforts as part of the NIAID biodefense research agenda.

Additional information on NIAID Category A, B, and C Priority Pathogens can be found on the NIAID Biodefense website:
http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/research/Pages/CatA.aspx
http://www.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/Documents/categorybandc.pdf
as well as:
http://funding.niaid.nih.gov/ncn/glossary/default5.htm
http://pathema.jcvi.org/pathema/AbcGenomes.shtml
http://www.fas.org/irp/threat/cbw/niaid0803.pdf

Category A
Bacteria
- *Bacillus anthracis* (Anthrax)
- *Clostridium botulinum* (Botulism)
- *Francisella tularensis* (Tularemia)
- *Yersinia pestis* (Plague)

Viruses
- Variola major (Smallpox) and other pox viruses
- Viral hemorrhagic fevers
  - Arenaviruses
    - Guanarito virus
    - Junin virus
    - Lassa virus
    - Lymphocytic choriomeningitis virus
    - Machupo virus
  - Bunyaviruses
    - Hantaviruses
    - Rift Valley fever virus
  - Flaviruses
    - Dengue fever viruses
  - Filoviruses
    - Ebola virus
    - Marburg virus

Category B
Bacteria
- *Burkholderia pseudomallei*
- *Burkholderia mallei* (Glanders)
- *Clostridium perfringens* (Epsilon toxin)
- *Coxiella burnetii* (Q fever)
- *Brucella melitensis*, *abortus*, *suis*, and *canis*
- *Staphylococcus aureus* (Enterotoxin B)
- *Rickettsia prowazekii*
- *Chlamydia psittaci*

- Food and Waterborne Pathogens
  - Escherichia coli O157:H7
  - Vibrio cholerae (Cholera)
  - Salmonella species
  - Shigella species
  - Listeria monocytogenes
  - Campylobacter jejuni
  - Yersinia enterocolitica

Viruses

- Viral encephalitis
  - West Nile virus
  - Eastern equine encephalitis virus
  - Western equine encephalitis virus
  - Venezuelan equine encephalitis virus
  - La Crosse virus
  - Japanese encephalitis virus
  - Kyasanur forest virus
  - California encephalitis viruses
- Food and Waterborne Pathogens
  - Caliciviruses (Gastroenteritis)
  - Hepatitis A virus (Hepatitis A)

Protozoa

- Food and Waterborne Pathogens
  - *Cryptosporidium parvum*
  - *Cyclospora cayatanensis*
  - *Giardia lamblia*
  - *Entamoeba histolytica*
  - *Toxoplasma gondii*
  - *Microsporidia*

Plants

- *Ricinus communis* Castor bean (Ricin toxin)

Category C

Emerging infectious disease threats such as Nipah virus and additional hantaviruses.
NIAID priority areas:

Bacteria

- *Coccidioides immitis* (added February 2008)
- *Coccidioides posadasii* (added February 2008)
- *Mycobacterium tuberculosis* (including multidrug-resistant Tuberculosis)
- Other *Rickettsia*

Viruses

- Chikungunya virus
- Influenza viruses
- Nipah virus
- Rabies virus
- Severe acute respiratory syndrome associated coronavirus (SARS-CoV)
- Tickborne hemorrhagic fever viruses
  - Crimean-Congo hemorrhagic fever virus
- Tickborne encephalitis viruses
- Yellow fever virus
- Other Hantaviruses

Prions

Antimicrobial resistance, excluding research on sexually transmitted organisms*

- Research on mechanisms of antimicrobial resistance
- Studies of the emergence and/or spread of antimicrobial resistance genes within pathogen populations
- Studies of the emergence and/or spread of antimicrobial-resistant pathogens in human populations
- Research on therapeutic approaches that target resistance mechanisms
- Modification of existing antimicrobials to overcome emergent resistance

Antimicrobial research, as related to engineered threats and naturally occurring drug-resistant pathogens, focused on development of broad-spectrum antimicrobials

Innate immunity, defined as the study of nonadaptive immune mechanisms that recognize, and respond to, microorganisms, microbial products, and antigens

***NIAID Category C Antimicrobial Resistance—Sexually Transmitted Excluded Organisms**

Bacterial vaginosis, *Chlamydia trachomatis*, Cytomegalovirus, *Granuloma inguinale*, *Hemophilus ducreyi*, Hepatitis B virus, Hepatitis C virus, Herpes Simplex virus, Human immunodeficiency virus, Human papillomavirus, *Neisseria gonorrhea*, *Treponema pallidum*, *Trichomonas vaginalis*

Appendix B

Compiled list of microorganisms and toxins used for biological defense research at the facilities reported in Form A Part 2(iii)

Microorganisms

Acanthamoeba castellanii
Acetivibrio ethanolgignens
Achromobacter xylosoxidans
Acidithiobacillus spp.
Acinetobacter baumannii
Actinobacillus equuli
Actinobacillus lignieresii
Actinobacillus pleuropneumoniae
Actinomyces naeslundii
Adeno-Associated virus
Adenoviruses
African swine fever virus (ASVF)
Alternaria spp.
Anaerobiospirillum
Anaeroplasma
Aspergillus flavus
Aspergillus niger
Aspergillus versicolor
Avian influenza virus
Highly Pathogenic Avian Influenza (HPAI) virus
Highly Pathogenic Avian Influenza (HPAI) virus (recombinant vaccine reference strains of H5N1 and H5N3 subtypes)
Avian metapneumonvirus

Bacille Calmette-Guérin
Bacillus anthracis
Bacillus anthracis (attenuated)
Bacillus anthracis (inactivated and vaccine strains only)
Bacillus anthracis (inactivated)
Bacillus anthracis (strains lacking the virulence plasmid pX02)
Bacillus anthracis (strains that are devoid of both pX01 and pX02)
Bacillus brevis
Bacillus cereus
Bacillus cereus (inactivated and BSL-1 strains only)
Bacillus circulans
Bacillus globigii
Bacillus globigii [atrophaeus] spores
Bacillus megaterium
Bacillus mycoides
Bacillus sphaericus
Bacillus subtilis
Bacillus thuringiensis (Bt)
Bacillus thuringiensis israelensis (Bti)
Bacillus thuringiensis Al Hakam
Bacillus thuringiensis kurstaki (Btk)
Bacteriophage
Bacteriophage MS2
Bacteroides fragilis
Bartonella henselae
Bifidobacterium dentium
Bluetongue virus (BTV)
Bluetongue virus (BTV), genetic material
Border disease virus
Bordetella avium
Bordetella bronchiseptica
Bordetella hinzii
Bordetella pertussis
Borrelia burgdorferi
Bovine adenovirus
Bovine astrovirus
Bovine calicivirus
Bovine herpes and retroviruses: Untyped
Bovine herpesvirus
Bovine lentivirus
Bovine papular stomatitis, genetic material
Bovine papular stomatitis virus
Bovine parainfluenza virus
Bovine parvovirus
Bovine respiratory syncytial virus (BRSV)
Bovine serum albumin (BSA)
Bovine spumavirus
Bovine viral diarrhea virus (BVDV)

Brachyspira alvinipulli
Brachyspira hyodysenteriae
Brachyspira innocens
Brachyspira pilosicoli
Brucella (killed)
Brucella abortus
Brucella abortus (killed)
Brucella canis
Brucella melitensis
Brucella melitensis (inactivated)
Brucella neotomae
Brucella ovis
Brucella spp.
Brucella suis
Brugia malayi
Burkholderia andropogonis
Burkholderia caryophylli
Burkholderia cepacia
Burkholderia gladioli
Burkholderia glumae
Burkholderia mallei
Burkholderia mallei (inactivated)
Burkholderia mallei (killed)
Burkholderia pseudomallei
Burkholderia spp.
Burkholderia thailandesis

Cache valley virus
Camel pox virus (CMPV)
Campylobacter coli
Campylobacter fetus
Campylobacter jejuni
Campylobacter jejuni (killed), nucleic acid
Campylobacter lari
Campylobacter sputorum
Canine calicivirus
Canine coronavirus
Canine parvovirus
Caprine adenovirus
Caprine herpervirus, genetic material
Caprine herpesvirus
Caprine lentivirus
Caprine respiratory syncytial virus
Caulobacter vibrioides
Cedecea neteri
Central European Tick-borne encephalitis virus
Cercopithecine herpesvirus
Chaetomium globosum
Chikungunya virus
Chlamydia trachomatis
Chlorella pyrenoidosa
Chlorella sorokiniana
Chromobacterium violaceum
Chronic wasting disease
Chryseobacterium spp.
Cla*dosporium cladosporioides*
Classical swine fever virus (CSFV)
Classical swine fever virus (CSFV), genetic material
Clavibacter michiganense
Clostridium argentinense
Clostridium botulinum
Clostridium botulinum (inactivated)
Clostridium botulinum, botulinum neurotoxin producing species
Clostridium butyricum
Clostridium difficile
Clostridium novyi
Clostridium perfringens
Clostridium perfringens, inactivated nucleic acid
Clostridium septicum
Clostridium sordelli
Clostridium sporogenes
Clostridium tetani
Clostridium tetani, inactivated nucleic acid
Coccidiodes immitis
Corona virus
Corynebacterium bovis
Corynebacterium pseudotuberculosis
Corynebacterium spp.
Cowpox virus (CPXV)
Coxiella burnetii
Coxiella burnetii (inactivated)
Coxiella burnetii (killed)
Coxiella burnetii, inactivated, nucleic acid
Coxsackievirus
Crimean-Congo hemorrhagic fever (CCHF) virus
Cytomegalovirus

Deer adenovirus
Deer adenovirus, genetic material
Deinococcus radiodurans
Dengue virus
Dengue virus, nucleic acid
Dengue/Langat Chimera
Dengue/TBEV Chimera
Dichomitus squalens

Eastern equine encephalitis virus (EEEV) (killed)
Eastern equine encephalitis virus (EEEV)
Ebola virus
Ebola virus (killed)
Ebola virus, genetic material
Ebola virus, protein
Encephalomyocarditis virus
Enteric viruses of poultry
Epizootic hemorrhagic disease virus
Equine adenovirus
Equine arteritis virus
Equine herpesvirus
Equine herpesvirus, genetic material
Erwinia herbicola
Erwinia herbicola (inactivated)
Erysipelothrix spp.
Escherichia coli
Escherichia coli (killed strain)
Escherichia coli 0157:H7 (killed)

Far-Eastern tick-borne encephalitis virus
Feline calicivirus
Feline infectious peritonitis virus
Feline parvovirus
Flavobacterium mizutaii
Flexal virus
Foot and Mouth Disease (FMD) virus
Fort Morgan virus
Francisella novicida
Francisella philomiragia
Francisella philomiragia (killed strain)
Francisella spp.
Francisella spp., genomic material
Francisella tularensis
Francisella tularensis (inactivated)
Francisella tularensis (killed strain)
Francisella tularensis (LVS)
Francisella tularensis (vaccine strain)
Fusarium oxysporum
Fusobacterium
Fusobacterium necrophorum

Goat pox virus
Guanarito virus

Haemophilus avium
Haemophilus paragallinarium
Haemophilus parainfluenzae
Haemophilus parasuis
Haemophilus somnus
Hafnia alvei
Halobacterium solanarium
Hanta virus
Helicobacter pylori
Hemorrhagic enteritis virus
Hendra virus
Herpes simplex virus
Human immunodeficiency virus (HIV)
Human noroviruses
Human noroviruses, genetic material
Human noroviruses, protein
Human papillomavirus

Infectious bursal disease virus (IBDV)
Influenza virus

Japanese Encephalitis (JE) virus
Junin virus
Junin virus (vaccine strain Candid 1)

Klebsiella pneumoniae
Kluyvera ascorbata
Kunjin virus
Kyasanur Forest disease virus

Lactobacillus casei
Lactobacillus lactus
Langat virus
Langat/TBEV chimera
Lassa virus
Legionella pneumophila
Leishmania amazonensis

Lentiviral vectors
Lentivirus Bovine immunodeficiency virus
Leptospira biflexa
Leptospira borgpetersenii
Leptospira inadai
Leptospira interrogans
Leptospira kirschneri
Leptospira noguchii
Leptospira santarosai
Leptospira weilii
Liberabacter africanus
Liberabacter americanus
Liberabacter asiaticus
Listeria monocytogenes
Lujo viros
Lymphocytic Choriomeningitis virus (LCMV)

Machupo virus
Magnaporthe grisea
Malignant cattarhal fever viurs, genetic material
Mannheimia glucosida
Mannheimia haemolytica
Marburg virus
Marburg virus (killed)
Marburg virus, genetic material
Marburg virus, protein
Marek's disease herpesvirus
Mink calicivirus
Modified Vaccinia Ankara (MVA) virus
Monkey pox virus
Moose adenovirus
Moraxella bovis
Moraxella spp.
Murid herpes virus
Murine hepatitis virus
Murine norovirus
Mycobacterium avium
Mycobacterium bovis
Mycobacterium kansasii
Mycobacterium paratuberculosis
Mycobacterium smegmatis
Mycobacterium tuberculosis
Mycobacterium tuberculosis, inactivated nucleic acid
Mycoplasma arginini
Mycoplasma capricolum
Mycoplasma conjunctivae
Mycoplasma gallisepticum
Mycoplasma ovipnuemoniae
Mycoplasma putrefaciens
Mycoplasma synoviae

Naegleria fowleri
Nannochloropsis
Near neighbors and look-alikes of the following agents: *Liberabacter africanus*, *Liberabacter americanus*, *liberacter asiaticus* and *Xylella fastidiosa*
Neisseria lactamica
Neisseria spp.
Neurospora crassa
Newcastle disease virus (NDV)
Nipah virus

Odocoileus adenovirus
Omsk Hemorrhagic Fever
Orf virus
Ornithobacterium rhinotracheale
Ovalbumin
Ovine adenovirus
Ovine lentiviruses
Ovine parainfluenza virus
Ovine respiratory syncytial virus

Parainfluenza virus
Pasteurella canis
Pasteurella dagmatis
Pasteurella gallinarum
Pasteurella haemolytica
Pasteurella langae
Pasteurella multocida
Pasteurella pnuemotropica
Pasteurella stomatis
Pasteurella trehalosi
Pasteurella ureae
Penicillium chryogenum
Penicillium funinculosum
Peronosclerospora phillipinensis
Peronosclerospora sacchari
Phakopsora pachyrhizi

Phanerochaete chrysosporium
Phoma glycinicola (formerly Peronosclerospora sacchari)
Phytophthora infestans
Phytophthora kernoviae
Phytophthora ramorum
Pichia pastoris
Pichinde virus
Pirital virus
Plum Pox Virus
Porcine adenovirus
Porcine astrovirus
Porcine calicivirus
Porcine circovirus
Porcine enterovirus
Porcine hemagglutinating encephalomyelitis virus
Porcine parvovirus
Porcine reovirus
Porcine reproductive and respiratory syndrome virus (PRRS, Porcine arterivirus)
Porcine respiratory coronavirus
Powassan virus
Prevotella nigrescens
Prions
Propionibacterium avidum
Proteus spp.
Pseudocowpox virus
Pseudomonas aeruginosa
Pseudomonas fluroescens
Pseudomonas oxalacticus
Psittacine herpesvirus
Puccinia graminis tritici
Puccinia striiformis
Puumala virus

Rabbit pox virus
Ralstonia solanacearum
Rathayibacter toxicus
Rhino virus
Rhizobium(Agrobacterium) radiobacter
Rhodococcus equi
Rickettsia prowazekii
Rickettsia prowazekii, genetic material
Rickettsia rickettsii
Rickettsia rickettsii, genetic material
Rickettsia spp.
Riemerella anatipestifer
Rift Valley Fever (RVF) virus
Rinderpest virus
Rinderpest virus, genetic material
Russian Spring and Summer encephalitis virus

Sabia virus
Saccharomyces cerevisiae
Salmonella bongori
Salmonella cholerasuis
Salmonella dublin
Salmonella enterica
Salmonella enteritidis
Salmonella mbandaka
Salmonella pullorum
Salmonella typhimurium
Salmonella typhimurium (killed)
San Miguel sea lion virus
Sclerophthora rayssiae
Scrapie
Semliki Forest virus
Sendai virus (SeV)
Serratia marcescens
Severe Acute Respiratory Syndrome virus (SARS)
Sheep pox virus
Shewanella oneidensi
Shigella dysenteriae
Shigella dysenteriae (killed)
Shigella ssp.
Sindbis virus
Skunk calicivirus
Soybean Dwarf virus
Sphingobacterium spp.
Squirrel fibroma virus
St. Louis encephalitis
Staphylococcus aureus
Staphylococcus aureus (inactivated)
Staphylococcus epidermidis
Staphylococcus hominis
Staphylococcus intermedius
Staphylococcus saprophyticus
Streptococcus agalactiae
Streptococcus bovis

Streptococcus dysgalactiae ssp.
Streptococcus intermedius
Streptococcus intestinalis
Streptococcus pneumoniae
Streptococcus pyogenes
Streptococcus uberis
Streptomyces lividans
Suid herpesviurs, genetic material
Swine enterovirus
Swine influenza virus

Tacaribe virus
Tatlockia maceachernii
Thermus aquaticus
Tick-borne encephalitis virus
Tick-borne flaviviruses
Toxoplasma gondii
Transmissible gastroenteritis virus
Transmissible mink encephalopathy
Treponema bryantii
Treponema denticola
Treponema hyodysenteriae
Treponema pallidum
Treponema phagedenis
Treponema succinifaciens
Trypanosoma cruzi

Vaccinia virus
Vaccinia virus (inactivated)
Vaccinia virus (killed)
Varicella zoster virus (VZV)
Variola major virus (Smallpox virus)
Variola major virus (Smallpox virus), genetic material
Venezuelan equine encephalitis (VEE) virus (inactivated)
Venezuelan equine encephalitis (VEE) virus
Venezuelan equine encephalitis (VEE) virus (killed)
Venezuelan equine encephalitis (VEE) virus (attenuated)
Vesicular stomatitis virus (VSV)
Vibrio cholerae
Vibrio cholerae (killed)
Vibrio cholerae, nucleic acid
Vibrio fisheri
Vibrio harveyi

Wangiella dematidis
Water buffalo adenovirus
West Nile virus (WNV)
Western equine encephalitis (WEE) virus
Western equine encephalitis (WEE) virus (killed)

Xylella fastidiosa

Yellow fever virus
Yersinia bercovieri
Yersinia enterocolitica
Yersinia intermedia
Yersinia pestis
Yersinia pestis (inactivated)
Yersinia pestis (killed)
Yersinia pestis (Lcr- strains)
Yersinia pestis (pgm-strain)
Yersinia pseudotuberculosis
Yersinia pseudotuberculosis (killed strain)
Yersinia rohdei
Yersinia ruckeri
Yersinia spp.

Toxins and Toxoids

Abrin
Aflatoxin
Anthrax Toxin

Brevetoxin

Cholera toxin
Clostridium botulinum neurotoxin A
Clostridium botulinum neurotoxin
Clostridium botulinum neurotoxin (inactivated)
Clostridium botulinum toxoids [not toxins]
Clostridium perfringens epsilon toxin
Conotoxin

Deoxynivalenol
Diacetoxyscirpenol
Diphtheria toxin
Domoic acid

Fumonisin

Marine toxins
Microcystin LR

Neosaxitoxin

Ochratoxin

Pertussis toxin

Ricin
Ricin (inactivated)
Ricin A chain

Saxitoxin

Shigatoxin
Staphylococcal enterotoxin
Staphylococcal enterotoxin B (SEB) toxoid

T-2 toxin
Tetrodotoxin