Responses Prepared by National Institute of Allergy and Infectious Diseases (NIAID) to Questions Posed by Containment Laboratory Community Advisory Committee
January 2012

1. **What is this institution's mission?**

The mission of the National Institute of Allergy and Infectious Diseases Integrated Research Facility at Fort Detrick (NIAID IRF) is to manage, coordinate and facilitate the conduct of emerging infectious diseases and biodefense research in order to develop medical countermeasures and improved medical outcomes for patients.

2. **What research are you conducting? How much of the research is considered dual-use?**

As of January 2012, the high-containment laboratory at the NIAID IRF is under construction, so no research is being conducted there at this time. Once research begins in this facility, we will diligently evaluate all scientific reports and manuscripts submitted for publication to guard against inadvertent disclosure of information that would enable malevolent use. The NIH Office of Biotechnology Activities (OBA) evaluates studies for potential dual use issues prior to the approval and initiation of the research. Additional information about the functions of various components of the NIH OBA is available here: http://oba.od.nih.gov/oba/index.html.

3. **What pathogens do you/ will you work with?**

We anticipate that the first focus of research when the NIAID IRF becomes operational will be viruses that cause hemorrhagic fevers such as Lassa, Marburg, Ebola and Hanta viruses.

4. **How large is this facility, i.e. square footage of BSL-3 and square footage of BSL-4?**

The BSL-4 space will occupy 11,000 total net square feet. That space can be partitioned into quadrants, so that 25 percent, 50 percent or 75 percent of the total can be operated at BSL-3 capacity if warranted.

5. **How many people will work in the labs?**

We project that the NIAID IRF will employ a maximum of 160 government and contract employees, including scientists and administrative and scientific support staff.

6. **Who runs the labs? Who does the contractor report to in the federal sector?**

The NIAID IRF is situated organizationally within NIAID's Division of Clinical Research (DCR). The IRF itself is headed by the Director, Integrated Research Facility at Fort Detrick. The Director, NIAID IRF, reports to the Director, DCR. The contractor for the NIAID IRF, Battelle Memorial Institute, receives guidance from the Director, NIAID IRF, and the Associate Director for Management and Operations, NIAID IRF.

7. **Will you conduct any classified research?**

No. The NIAID IRF will not conduct any classified research.

8. **Who decides what research you will conduct?**

The NIAID IRF research portfolio is being determined by the NIAID IRF Director in consultation with a scientific steering committee composed of senior executives of NIAID and the National Institutes of Health (NIH) Clinical Center. One task of the scientific steering committee, working with the NIAID IRF Director and Senior Management Team, is to develop an annual research portfolio for the NIAID IRF.

9. **What is the status of the new building? When will the building go hot? What were the issues with the building that delayed its commissioning and what is being done to address them?**

As of January 2012, the NIAID IRF high-containment laboratory is under construction; activities to support the eventual commissioning of the lab are ongoing. (Commissioning is a systematic process, through documented verification, that all building systems are performing according to the design intent and owner's operational needs.) Commissioning will begin once we are sure all systems are operating at full capacity and efficiency.

At this time, we cannot predict with certainty when the NIAID IRF will complete its commissioning, endurance testing and U.S. Centers for Disease Control and Prevention (CDC) certification processes. (Endurance testing is a process lasting 30 consecutive days during which lab personnel simulate operation of the lab under BSL-4 conditions to confirm functional and operational readiness. Certification by the CDC entails demonstration of compliance with all engineering and operational requirements plus appropriate training and background clearance for personnel with access to Select Agents.) We expect that these processes will be completed and the NIAID IRF will be fully operational at the BSL-4 level in the 2012-2013 timeframe.

10. **How do you coordinate with the other NIBC labs re: potential accidents, events or emergencies?**

In the event of an emergency, the affected NIBC partner would contact the U.S. Army Garrison, which would respond with needed resources. The Garrison functions as a hub to coordinate among all NIBC partners.

Routine collaboration among partner agencies is maintained via twice monthly meetings of the Fort Detrick Interagency Coordinating Committee. Among the activities of the Coordinating Committee are emergency response drills and tabletop exercises to test incident response activities. The NIAID IRF Associate Director for Program Integration is responsible for communications and cooperative efforts with other NIBC labs and the U.S. Army Garrison.

11. **How do your biosecurity, biosafety and personnel reliability programs differ from USAMRIID's?**

While details and lines of reporting may differ from those followed by USAMRIID, the biosecurity, biosafety and personnel reliability programs of the NIAID IRF do not differ in principle from USAMRIID's. For example, best practices for safe handling of infectious agents

and toxins (biosafety) are detailed in the standard manual, "*Biosafety in Micobiological and Biomedical Laboratories, 5th edition* (BMBL). This resource is produced by the CDC and is available in full here: http://www.cdc.gov/biosafety/publications/bmbl5/index.htm. The BMBL also includes a discussion of biosecurity in high-containment settings.

The NIH Division of Occupational Health and Safety (DOHS) directs and implements the biosafety program on site at the NIAID IRF at Ft. Detrick. Biosecurity and the biological surety program (BSP) are part of the NIH's overall bio-risk management approach. Personnel reliability is part of the NIH BSP. Personnel reliability includes: medical clearance, appropriate and available immunizations; behavioral health screening, background investigation, and FBI Security Risk Assessment; NIH Collective Foreign Threats Screening and a personal interview with the NIH Certifying Official. The personnel reliability checks are completed annually.

Numerous resources on such topics as laboratory safety and employee and laboratory compliance with applicable regulations are collected on the web site of the NIH DOHS: http://www.ors.od.nih.gov/sr/dohs/Pages/default.aspx.

12. **What are your memoranda of understanding with Fort Detrick, city and county, hospital vis a vis emergency preparedness?**

Under established agreements, all tenants at the Fort Detrick installation receive fire, police and hazardous materials assistance from the U.S. Army Garrison as needed in the event of an emergency. In addition, the U.S. Army Garrison has formal agreements in place with the City of Frederick and Frederick County for additional emergency support if needed.

Furthermore, the NIH has a Memorandum of Agreement with Frederick Memorial Hospital, Frederick County, Md. Among points of agreement is the willingness of the hospital to provide emergency care to ill or injured NIAID IRF workers who require critical care, but who have not been exposed to any infectious agent in the laboratory. For example, if a worker suffers a heart attack while working in the high-containment lab, emergency care will be provided by the hospital.

13. **Who do officials call to get health and safety-related information? Who does the Frederick Public Health Department call with questions?**

We have established direct lines of communication between the Chief Medical Officer for the NIAID IRF and officials with the Frederick Public Health Department (FPHD). In the event of an incident or emergency, the U.S. Army Garrison, the Chief Medical Officer, NIAID IRF, and FPHD officials will be in communication as needed to address the incident.

General inquiries about the NIAID IRF from the media, the general public or local officials should be directed to the NIAID Office of Communications and Government Relations public inquiries line at 1-866-284-4107 or Ocpostoffice@niaid.nih.gov.

14. **Who decides when a worker may need to be quarantined or treated? Who else is that decision coordinated with?**

If a worker is exposed to an infectious agent, a decision regarding whether to admit the worker to the Special Clinical Studies Unit (SCSU) at the NIH Clinical Center is made by the Director, Occupational Medical Service, NIH. The decision is coordinated with the Chief Medical Officer, IRF; infectious disease subject matter experts at the NIH; and the management staff of the SCSU.

15. **Where would infected workers be treated? How do they get there?**

If it is determined that an exposed worker requires admission for further observation or treatment, he or she would be securely transported in a specially equipped isolation ambulance (owned by the U.S. Army Garrison) from the NIAID IRF to the SCSU in Bethesda, Md.

16. **In case of accident, incident or emergency what triggers public notification? When is the public notified and by whom?**

In the event of an accident or emergency, the NIAID IRF would immediately notify the U.S. Army Garrison, which would activate appropriate emergency response personnel and also alert Frederick area emergency responders as needed.

The public at large is notified about emergencies that have occurred at Fort Detrick by the U.S. Army Garrison command.

17. **How often do your institutional biosafety committees meet; who generally serves on them, i.e. from what internal and external organizations?**

The NIH Institutional Biosafety Committee (IBC) meets monthly in Bethesda, Md. The current membership and institutional affiliations are available here: http://www.ors.od.nih.gov/sr/dohs/SafetyResources/committees/Pages/inst_biosafety_committee.aspx. The committee includes representatives from the general public. The charter of the NIH IBC is detailed here: http://oma.od.nih.gov/manualchapters/management/1340/

18. **What is your external safety review program and who does the reviewing?**

The Division of Occupational Health and Safety, (DOHS) in the Office of Research Services, Office of the Director, NIH, has continuous oversight of the NIAID IRF and insures compliance with all applicable regulations including engineering and operational controls required by the CDC Division of Select Agents and Toxins. Once certified by CDC, the IRF will be re-inspected by CDC on a periodic basis.

19. **From NIAID-IRF's perspective, how specifically do you coordinate on community health and safety and emergency preparedness with the rest of NIBC? How does the management structure interface with the rest of NIBC and the garrison?**

The NIAID IRF management structure interfaces with NIBC components and the U.S. Army Garrison through the NIAID Associate Director for Program Integration. This official is a part of the senior level management team for the NIAID IRF and the Fort Detrick Interagency Coordinating Committee (FDICC).

In addition to participation in the NIBC, the NIAID is also a signatory to the National Interagency Confederation for Biological Research (NICBR). The NICBR was formed in 2002 to facilitate and coordinate planning, management, and scientific interactions among the agencies co-located at Fort Detrick. Among the objectives of the NICBR is the establishment of processes for coordinating and synchronizing areas of common interest among the federal agencies involved in medical research and/or biotechnology at Fort Detrick in order to encourage most efficient management practices, foster scientific interchange, and maximize productivity of research and biotechnology development among the signatories.