

**Guidance to Investigators for Proposals to NIH and other PHS agencies using
SF424 (R&R)
Research Plan, 5.5.11 (Select Agent Research)**

1. Identify the Select Agent(s) to be used in the proposed research.

PI lists any and all Select Agents to be used in the specific proposal. Select Agents Lists may be found at the following link:

<http://tulane.edu/asvpr/biosafety/selectagent/salists.cfm>

2. Provide the registration status of all entities* where Select Agent(s) will be used.

Tulane University is currently registered for possession and use of Select Agents. Registration number: CDC# C20110311-1198

· **If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where Select Agent research will be performed.**

3. Provide a description of all facilities where the Select Agent(s) will be used.

Tulane University operates a registered Select Agent laboratory at the Tulane National Primate Research Center. The facilities include approximately 800 square feet of BSL-3 laboratory space and 700 square feet of ABSL-3 animal holding and procedure rooms, including an aerobiology facility with Class III BSC.

· **Describe the procedures that will be used to monitor possession, use and transfer of the Select Agent(s).**

At Tulane University, only those individuals who have received a Department of Justice Security Risk Assessment and have been added to the TU Select Agent Registration are permitted to possess, use, or have access to any Select Agent. All Select Agents are stored within a Select Agent registered space under a stringent access and inventory control system monitored and audited by the Office of Biosafety and the RO and ARO. All Select Agents are transferred between an individual approved to possess them directly to a licensed commercial carrier or received from a licensed commercial carrier. All transfers occur only after CDC approval and will follow all regulations governing Select Agent transfers. Any intra-entity transfer at Tulane University will be conducted following approval and under the supervision of the Office of Biosafety and the RO or ARO and will be allowed only between individuals registered to possess the agent.

· **Describe plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).**

Tulane University has developed and implemented a Biosafety Plan and a Security Plan establishing policy and procedures that ensure the safe handling, containment, and security of areas containing Select Agents and toxins in accordance with 42 CFR 73. The Biosafety Plan addresses all practices and procedures involving the handling of Select Agents, entry and exit procedures including proper PPE, disinfection and decontamination procedures, spill and adverse incident responses.

The Biosafety Plan also describes the physical biocontainment requirements for the facilities where Select Agents are stored and handled, as well as the occupational health surveillance program and dual use research of concern review policy. The Security Plan is based on a systematic approach in which threats are defined, vulnerabilities are examined, and risks associated with those vulnerabilities are mitigated with a security systems approach. The Security Plan applies to all employees working at and all persons visiting TNPRC and identifies the roles and responsibilities of all individuals involved in establishing security standards for the protection of Select Agents and other assets such as access control, keys and locks, physical security, and the personnel suitability assessment.

Describe the biocontainment resources available at all performance sites.

All registered Select Agent facilities at Tulane University are certified annually as BSL-3 or ABSL-3 facilities and conform with the NIH Construction guidelines for BSL-3/ABSL-3 facilities, as well as the sections of the 5th Edition of the BMBL concerning BSL-3 and ABSL-3 facilities. These include single pass HEPA filtered exhaust balanced to provide differential pressures and directional air flow, multiple secured locked doors with restricted access, validated autoclaving of all waste exiting the facilities, and a tissue digester for disposal of animal tissues and carcasses.

Reviewers will assess the information provided in this Section, and any questions associated with Select Agent research will need to be addressed prior to award.

In addition to the Select Agent section, in the revised NIH “Facilities and Other Resources” section, the following discussion is required: “Describe any special facilities used for working with biohazards or other potentially dangerous substances. Note: Information about Select Agents must be described in the Research Plan, 5.5.11 (Select Agent Research).”

This section of the proposal will be highly variable and dependent on the individual research project. The Office of Biosafety (988-0300) will provide assistance and guidance with this section as needed.

In cooperation with the Institutional Biosafety Committee, the Office of Biosafety provides oversight of regulatory compliance at Tulane University with regard to the storage, use and shipping of hazardous biological materials. The Office of Biosafety will assist investigators in registering their research with the Institutional Biosafety Committee, provide technical assistance with developing safe research protocols, and facilitate the acquisition of all required regulatory approvals and permits.