University of Michigan
Institutional Biosafety Committee - BSL3 Subcommittee Charge

Background

Federally regulated Select Agents and Toxins ("Select Agents") used in research require specialized advance and ongoing review and approvals, and involves significant start-up and continuing costs to the University of Michigan. U-M therefore has established a process for review of proposals to use Select Agents and other BSL3 agents that not only ensures that legal and regulatory requirements are met but also ensures the appropriate institutional discussions take place before approvals are given. The U-M has designated a Responsible Official to guide faculty members through the process of review and approval. Deans and department chairs in units housing the research will be included in the review process. Explicit approval by the Vice President for Research will be required for BSL3 activities meeting specific criteria.

IBC BSL3 Subcommittee

The Vice President for Research has established a BSL3 Subcommittee of the U-M Institutional Biosafety Committee (IBC) to review proposals for research that would require the use of BSL3 containment facilities at U-M. This research may involve federally regulated Select Agents that require special review and oversight of security as well as safety measures. The BSL3 Subcommittee is further designated as the standing Institutional Review Entity required for identification and review of Dual Use Research of Concern (DURC), as specified in the US Government Policy on Institutional Oversight of Life Sciences Dual Use Research of Concern (hereafter "USG Policy").

Explicit approval by the Vice President for Research will be required for Principal Investigators new to performing research with a Select Agent, the commissioning of new BSL3 facilities, the use of a Select Agent not previously existing on campus, or research assessed to have Dual Use Research of Concern potential. The Responsible Official in consultation with the BSL3 Subcommittee will determine which activities meet the criteria to require explicit approval by the Vice President for Research.

The Responsible Official is the ultimate authority with jurisdiction on the U-M campus to approve (following approval by other locally-designated entities) or to disapprove the use of and access to Select Agents. The roles and responsibilities of the Responsible Official are detailed in the "U-M Select Agent Program" document from U-M's Department of Occupational Safety and Environmental Health (OSEH). The responsibilities of the Responsible Official include monitoring the Personnel Suitability Assessment Program, which is a federal requirement for access to Tier 1 Biological Select Agents and Toxins (Tier 1 BSAT). The Responsible Official has designated the BSL3 Subcommittee as the "Certifying Official Review Board," which receives reports from and provides recommendations to the Responsible Official pertaining to personnel suitability assessments.

The U-M IBC and its BSL3 Subcommittee endeavor to coordinate and cooperate with other relevant oversight bodies, such as the University Committee on Use and Care of Animals (UCUCA), to enhance the efficiency and effectiveness of the overall oversight of BSL3 related activities.

Composition of the IBC BSL3 Subcommittee

The BSL3 Subcommittee shall be comprised of no fewer than five members so selected that they collectively have experience and expertise in BSL3 technology and the capability to assess the safety and security of BSL3 facilities, operations, and activities in order to identify and address any potential risks. Each U-M school or college unit that houses a BSL3 facility within its space (e.g., the Medical School Department of Microbiology and Immunology, and the Medical School Unit for Laboratory Animal Medicine) will be represented on the Subcommittee by at least one member. Ex officio, voting members will include the University's Responsible Official for Select Agents. Ex officio, non-voting members will include the Medical School Associate Dean for Regulatory Affairs, a senior member of the University security community, a senior facilities representative from each school hosting a BSL3 facility, and a Human Resources representative. The Vice President for Research will appoint the chair and the members of the BSL3 Subcommittee for renewable three-year terms. The chair of the BSL3 Subcommittee will be an ex officio non-voting member of the IBC. Other members of the BSL3 Subcommittee may be members of the IBC. The BSL3 Subcommittee may also include individuals who are not members of the IBC but who bring particular expertise relevant to the oversight of BSL3 research and facilities.

Committee Responsibilities

The BSL3 Subcommittee's responsibilities will include:

- Review of all U-M BSL3 and ABSL3 facility (both laboratory and animal housing) commissioning reports, inspection reports, reports from facility directors and managers, reports on the adequacy of resources, plans for introduction of new agents into the facilities, and storage of agents;

- Review of reports from the Responsible Official regarding the ongoing management of all U-M BSL3 and ABSL3 facilities (both laboratory and animal housing) by the Facility Directors, with particular respect to biosecurity matters;

- Receipt of verification from the Responsible Official of the FBI Criminal Justice Information Services (CJIS) reported Security Risk Assessment (SRA) status for each individual to be granted access to Select Agents as part of each facility use approval and renewal. Only individuals with a documented CJIS SRA status of "SRA Approved" will be granted access to Select Agents;

- Receipt, in its capacity as the Certifying Official Review Board, of verification from the Responsible Official of the personnel suitability clearance (pre-access and ongoing) for each individual to be granted access to Select Agents or Toxins as part of each facility use approval and renewal, and provide recommendations to the Responsible Official concerning access decisions in response to reported information;

- Recommendation to the IBC of approval or disapproval of the proposed uses of U-M BSL3 and ABSL3 facilities through review of information submitted by principal investigators, including assessment of the proposed research, assessment of the biosafety risk profile of the agents to be used, the biosecurity/biosafety containment arrangements, facilities, procedures (including emergency procedures), practices, training, expertise, and evidence of project merit (including scientific). This approval will be in effect for a specified period of time not to exceed three years, and will require progress reports from the approved user at specified intervals not to exceed one year;

- Determination, in its capacity as the Institutional Review Entity, of whether research with specified agents and toxins meets the definition of Dual Use Research of Concern (DURC), and if DURC is identified, development of a risk mitigation plan in consultation with the federal funding agency. These duties are performed in accordance with USG Policy and the corresponding U-M Policy on DURC Oversight.

- Consultation to the IBC and University leaders on topics associated with BSL3 safety and security issues, and coordination with University Public Relations on representation for the University concerning U-M BSL3 facilities and issues;

- Reference of disputes associated with the management, operation, or use of the U-M BSL3 and ABSL3 facilities to the proper University officials.

The BSL3 Subcommittee will meet at least once per year and as often as necessary to carry out these responsibilities. The Responsible Official will provide a report to the Subcommittee at each meeting on regulated Select Agents being used or stored at U-M. Any applications and reports associated with the BSL3 Subcommittee and U-M BSL3 and ABSL3 facilities will be held confidential to the extent required by federal and state regulations and statutes, and University policy.