

Introductory Guide for Faculty Members Planning to Use Select Agents in their Research

Use in research of federally regulated Select Agents and Toxins (“Select Agents”) requires specialized advance and ongoing review and approvals, and involves significant start-up and continuing costs to the University. The University, therefore, has established a process for review of proposals to use Select Agents that not only ensures that legal requirements are met but also ensures that appropriate academic discussions take place before approvals are given.

What are Select Agents? (<http://www.cdc.gov/od/sap/docs/salist.pdf>)

Select Agents are microorganisms or related toxins that have been specifically identified by the federal government as presenting a potential public health threat as agents of bioterrorism. Identified and regulated as such, these agents carry additional regulatory burdens for safety and security.

What constraints are imposed on researchers planning to use Select Agents in their research?

The USA Patriot Act and follow-on legislation and regulation require the University to impose administrative controls and oversight over individuals with access to Select Agents and over locations where Select Agents are stored or used. Specifically, individuals may not be given access to Select Agents without special FBI clearance. Laboratories or storage locations must have specific types of enhanced physical security and electronic security over information on the agents and how they are stored and used (cybersecurity).

How do I learn more about the constraints on individuals?

The [OSEH document, “U-M Select Agent Program”](#) describes the administrative systems for managing this area of oversight including the plan for screening individuals who will have hands-on access to these agents.

How do I begin the process of proposing use of Select Agents?

Since the approval process is complicated and involves many University offices and federal agencies, the University has designated a **Responsible Official** (Janet Follo, 734-647-3133) to guide faculty members through the process. The first step is a quick feasibility study to establish rough estimates of numbers of individuals who will need federal clearance, the biological safety of the agent, the suitability of the security of the proposed location for use of the agent, and the financial costs. This information will then be provided to the department chair, the dean, and in some cases ultimately to the Vice President for Research who will decide whether the University can engage in the proposed research. Explicit vice presidential approval will be required for principal investigators new to performing research with a Select Agent, new facilities, and for use of Select Agents not previously existing on campus. The Responsible Official in consultation with the IBC BSL3 Subcommittee will determine which activities meet the criteria to require explicit approval by the Vice President for Research. An authorization form may be used to organize the information to be submitted to the Vice President for Research.

How do I initiate IBC registration of Select Agents work that also involves recombinant DNA?

The Institutional Biosafety Committee has a role in reviewing Select Agents work regardless of whether it involves recombinant DNA. For Select Agents work that does involve recombinant DNA, investigators must submit a recombinant DNA registration to the IBC in hard-copy (NOT over e-mail) to describe the work. To do this, please print off a copy of the appropriate rDNA registration, write or type in your answers, and hand deliver the registration, marked confidential, to the IBC at 4080 Fleming Bldg. A meeting will then be scheduled for the committee to discuss the proposal.

For more information:

- [UM Select Agent Program \(OSEH\)](#)
- [Institutional Biosafety Committee \(IBC\)](#)
- [National Select Agent Registry](#)