



Subject: Select Agent Transfers

Guide No: BLS002

Date: 06-01-03

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SUMMARY:

Researchers who wish to obtain or transfer Select Agent pathogens or regulated amounts of Select Agent toxins, specifically listed by CDC and USDA, must follow the procedures in this Guideline. Federal law requires the University to apply for and obtain a registration specific for each Primary Investigator who wishes to work with these highly-regulated materials, because they have the capacity to cause substantial harm to public health.

SCOPE: This Guideline applies to any researcher who wishes to obtain or transfer Select Agents as defined listed under current regulations.

**REFERENCE
REGULATIONS:**

- [CDC - Possession, Use, and Transfer of Select Agents and Toxins](#) (42 CFR 73)
- [USDA - Possession, Use, and Transfer of Biological Agents and Toxins](#) (7 CFR 331)
- [Bioterrorism Preparedness and Response Act of 2002](#) (HR 3448, Public Act 107-188)
- [USA Patriot Act of 2001](#) (HR 3162, Public Act 107-56)

DEFINITIONS:

Biosafety Manual - A required laboratory quality control and safety document, prepared by the PI to instruct staff on standard operating procedures for safe storage, use, and disposal of biohazardous materials. This is a requirement for obtaining and using select agent pathogens.

Biosecurity Plan - A document of institutional policy and procedure, describing the administrative processes necessary for compliance with the Select Agent regulations. Specific details concerning personnel and laboratory security, review and oversight by academic administration, institutional and federal registration, audit criteria, recordkeeping, and incident reporting are all given in the format required under federal regulations.

Chemical Hygiene Plan (CHP) - A required laboratory quality control and safety document, prepared by the PI to instruct staff on standard operating procedures for safe storage, use, and disposal of chemically hazardous materials. This is a requirement for obtaining and using select agent toxins.

Exemptions - There are research and clinical exemptions to the current regulations governing Select Agents. Clinical laboratories that participate in proficiency testing are allowed to receive and use reference specimens without having to undergo the registration process. Research exemptions exist for minimal quantities of select agent toxins. The limits for each toxin are identified on the attached list. No quantity exemptions are provided for live



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select agent pathogens. Exemptions for vaccine strains of Select Agents may be provided over time. Check with OSEH for the most current list.

Institutional Biosafety Committee (IBC) – The research administrative oversight body chartered by the Regents of the University to function under the authority of the Vice President for Research. Formal charter calls for oversight with approval authority for all research involving recombinant DNA and select agent materials acquisition and use.

Proficiency Testing – A function of clinical laboratories and an area exempted, somewhat, from the current Select Agent regulations. CDC-sponsored, time-limited analytical trials whereby one or more select agents, previously confirmed, are submitted to the reference or clinical testing laboratory for analysis and where final results are graded, scores are recorded and provided to participants, and scores for participants are evaluated. CDC and/or USDA requires the destruction of these reference specimens once evaluation is completed.

Requestor – If a researcher at University of Michigan wishes to obtain (order and receive) a select agent from an outside source, either academic or commercial, he/she becomes a requestor and must begin the application process through the RO. This initiates a screening process, described in the Biosecurity Plan, to qualify and privilege the researcher to receive and use the select agent in compliance with current regulations.

Responsible Official (RO) – Under current regulations promulgated by CDC and USDA, the university must identify and authorize two university officials to oversee the Select Agents compliance program. The RO's must: have authority and responsibility to ensure that the requirements of the part 73 are met, on behalf of the university; be familiar with the requirements of the part 73 regulations; and Be approved for access to biological agents and toxins under § 73.8. The Institutional Biosafety Officer is the RO for University of Michigan; the Director of Occupational Safety and Environmental Health (OSEH) serves as alternate RO.

Select agent – Specifically regulated pathogens and toxins as defined in Title 42 CFR Part 73, and listed by both by both DHHS and USDA (i.e., overlapping agents or toxins).

Supplier – If a researcher at University of Michigan wishes to provide a select agent specimen to another institution for research purposes, they become a supplier and must initiate a pre-screening process through the RO to assure that all necessary institutional and federal approvals are obtained prior to shipment of the material to the requestor.



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Transfer Request Form – Federal EA-101 form, prepared by OSEH on behalf of the requestor, which carries all pertinent information on the transfer of a select agent from one institution to another. The form tracks the transfer from “cradle to grave”; ending with a record of the complete use or destruction of the select agent by the recipient.

RESPONSIBILITY:

Deans, Directors and Department Heads

Assure that all principal investigators are aware of procedures contained in this Guideline.

Principal Investigators/Registered Users

Implement procedures for obtaining or transferring select agents in accordance with this Guideline.

Implement security and accountability procedures in accordance with the institutional Biosecurity Plan.

Register existing collections of select agents with OSEH's Biosafety Officer (BSO).

Prepare the biosafety manual and/or chemical hygiene plan as appropriate for their particular select agent use.

Provide or arrange for required training for their research staff, including biosecurity, biosafety, and chemical safety.

OSEH

Receive and process requests for registration and transfer of select agents.

Provide all necessary application and review documents to institutional and federal oversight agencies.

Maintain all required records associated with Select Agent use and destruction.

Provide internal audit services to document the biosecurity of regulated materials.

Represent the institution during external audit by federal agencies.

Maintain the UM registration (licensure) to possess Select Agents.

Provide generic documents and technical support necessary for researchers to prepare safety procedures for the use of Select Agents.

Witness and properly document the destruction of Select Agents.



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Office of the Vice President for Research (OVPR)

Provide the required oversight by Academic Administration, through the Institutional Biosafety Committee (IBC), to review the applications for Select Agent registration prior to submittal to the federal authorities (CDC/USDA).

Department of Public Safety (DPS)

Provide expertise for security measures in accordance with the institutional Biosecurity Plan.

Provide the necessary security background checks for select agent applicants through Department of Justice.

Participate along with OSEH in internal audits of biosecurity.

TRANSFER PROCEDURES:

Transfers to UM from outside entities

- UM Requestor provides written indication to the outside institution that they wish to receive a select agent specimen. It is required that they inform their RO to initiate the paperwork process for transfer approval.
- UM RO receives a phone call or email from the RO of the outside institution, and provides information sufficient to demonstrate UM registration to receive the select agent material. Additionally, an internal feasibility study is conducted by the Vice President for Research to determine if the transfer is institutionally appropriate. Portions of this study may be conducted by the Institutional Biosafety Committee.
- UM RO assists the UM Requestor in filling out the necessary portions of the EA-101 transfer request form, and faxes it to the RO of the outside institution and the CDC office of Select Agent Transfer (LR/SAT).
- RO of the outside institution completes the remaining portions of the form, receives the transfer permit from the CDC, and sends the completed document set to their IBC Chair for consideration.
- Upon approval by the IBC of the outside institution, their RO assists the Supplier in packing and shipping the select agent specimen to the UM RO at the OSEH Main Office, 1239 Kipke Drive.
- Upon receipt of the select agent transfer, UM RO provides notification to the RO of the outside institution. UM RO hand-delivers the select agent to the Requestor, and assures it is placed in secure storage according to the Institutional Biosecurity Plan.
- UM RO faxes a copy of the completed document set to the CDC-LR/SAT office.



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Transfers from UM to outside entities

- UM Supplier receives a written indication from an outside institution that they wish to receive a select agent specimen. PI passes this correspondence on to the UM RO to begin the paperwork and review process.
- UM RO contacts the RO of the receiving institution and the CDC to assure they are registered to receive the select agent specimen – this is a required investigation. Additionally, an internal feasibility study is conducted by the Vice President for Research to determine if the transfer is institutionally appropriate. Portions of this study may be conducted by the Institutional Biosafety Committee.
- UM Supplier receives the EA-101 transfer (request) form from the requestor, completed for those portions indicated for the requestor, fills-in the portions required for the supplier, and faxes the form to the UM RO.
- UM RO completes the remaining portions, receives the transfer permit from the CDC, and sends the completed document set to the IBC Chair for consideration.
- UM RO provides technical assistance to the UM Supplier for the packaging and shipment to the outside institution.
- UM RO receives confirmation of receipt from the RO of the receiving institution.

Biosafety Manual

A completed version of the [UM Biosafety Manual](#) is required for a laboratory to obtain and safely use select agent pathogens. The UM Biosafety Manual is based upon the NIH Guideline "Biosafety in Microbiological and Biomedical Research Laboratories" most recent ed., which gives minimal requirements for biosafety. However, the UM generic document gives specific information about institutional expectations for biological safety practices and instruction of staff in best practices. The Laboratory Director must assure that this generic document is converted to a laboratory-specific operational plan, with specific Standard Operating Procedures to meet their particular biohazards and containment needs.

NOTE: This Biosafety Manual will also accommodate any Recombinant DNA research biosafety issues you may need to address. If your laboratory works with human blood or tissues, an [Exposure Control Plan](#) is required. This generic plan can be found at the OSEH Web Site.

Chemical Hygiene Plan (CHP)

Under the MIOSHA-Laboratory Safety Standard and CDC rules, a completed version of the [UM Chemical Hygiene Plan](#) is required for a laboratory to obtain and safely use select agent toxins. The CHP must include specific work practices, procedures, and policies to ensure that employees are educated about the hazards of their work and instructed on prudent practices and mandatory precautions.



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Material Transfer Agreement (MTA)

It may be necessary for a UM Supplier to obtain an MTA when seeking to transfer a Select Agent specimen to a Requestor at another institution. MTA forms can be obtained from the UM Department of Research Development Administration office of Corporate Contracts and Technology Transfer (CCTT).

U.S. Department of Commerce

In order for a UM Supplier to transfer a Select Agent specimen to a Requestor in another country, they must obtain approval from U.S. Department of Commerce. Commerce Department application form (BXA-748P) can be obtained from the UM Department of Research Development Administration – CCTT office.

**RELATED
DOCUMENTS:**

UM – Institutional Biosecurity Plan

CDC/NUIH Guideline - Biosafety in Microbiological and Biomedical Laboratories, most recent ed.

UM-OSEH Guideline – [Biosafety Manual](#)

UM-OSEH Guideline – [Exposure Control Plan](#)

UM-OSEH Guideline – [Chemical Hygiene Plan](#)

UM-OSEH Guideline – [Patriot Act](#)

**TECHNICAL
SUPPORT:**

All referenced guidelines, regulations, and other documents are available at OSEH (3-6973).

ATTACHMENTS: Appendix A – [CDC/USDA Select Agents List](#)