

Biological Safety Regulatory Highlights for MSU Researchers

This document has been prepared as a summary of biosafety-related regulatory considerations for researchers at MSU. For further information, please refer to the MSU Biosafety Manual, the "Biosafety in Research" website (www.biosafety.msu.edu), or contact the ORCBS Biosafety Staff at 355.0153.

Recombinant DNA Molecule Use Registration & Review

All work involving recombinant DNA molecules at MSU is subject to the NIH "Guidelines for Research Involving Recombinant DNA Molecules." These guidelines address the safe conduct of research that involves construction and handling of recombinant DNA molecules and organisms containing them. The NIH defines recombinant DNA molecules as molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or molecules that result from the replication of those previously described.

MSU researchers who are using recombinant DNA molecules as part of their research must file a registration document with the Institutional Biosafety Committee (IBC), regardless of the funding source or NIH review category. The IBC will review all registrations and provide recommendations and approvals as appropriate. The ORCBS Biosafety Staff supports the review process by assisting researchers with registration preparation or revision, training and lab inspections as needed.

The most recent edition of the NIH guidelines can be found online in the recombinant DNA section of the "Biosafety in Research" website. Hard copies are also available upon request. Please contact Amber Bitters, Biosafety Industrial Hygienist, at 432-5262 or email at bitters1@msu.edu for further information.

Impact of non-compliance:

- Increased risk of releasing genetically-modified materials which could be hazardous to lab personnel and the environment at large,
- May cause delays in receiving funds from granting agencies,
- May cause delays in project approval by institutional review committees (IACUC, UCRIHS, IBC),
- May result in loss of NIH funds for MSU.

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DHHS/USDA Select Agents Regulation

Infectious agents and toxins that are considered by the Department of Health & Human Services (DHHS) or the United States Department of Agriculture (USDA) as having the potential to pose substantial harm or are a severe threat to human, animal or plant health or plant products are regulated as “select agents.” These restricted materials appear in the list on the following page.

Possession and transfer of materials on this list (with the possible exception of toxins) requires registration with, and approval of the appropriate regulatory authority by way of the MSU Responsible Official (RO) prior to undertaking such activities. Please contact Dr. Jamie Sue Willard, Biosafety Officer (and Responsible Official) at 353-1877 or email at *cherryme@msu.edu*. More information regarding select agent requirements is also available at the “Biosafety in Research” website under the “select agents” link.

What You Need To Know...

It is essential for all departments who conduct research with biological materials to be aware of the select agents list and the need for notification and registration of select agent use. As our campus and research endeavors continue to grow, so does the potential for select agent use.

Departments & Research Personnel must adhere to the following:

- When considering research/faculty candidates, departments must inquire about any intentions of the candidate to conduct work with select agents. A select agents declaration form must be completed and submitted to the RO by way of the department by incoming faculty before they begin work at MSU. Specific facility, administrative and training requirements as well as federal security clearance must be completed before select agent work can begin.
- Before visiting research personnel from other countries come to campus, hosting departments must assure that these visitors are aware of the select agents regulations and restrictions. If such personnel plan to bring select agents with them or conduct work with select agents during their work at MSU, the hosting department must contact the ORCBS well in advance of the visitor's arrival.

Impact of non-compliance:

- These regulations were written and implemented in the United States to combat terrorism. Any unauthorized possession and/or use of these materials at this time must be reported to the appropriate federal agency via the institutional RO.
- Failure to report any unauthorized possession and/or use of these materials, or lack of cooperation with federal authorities is likely to result in criminal penalties.

A Note to Toxin Users...

If you are planning to conduct research using a toxin on this list, you must contact the ORCBS to complete documentation related to intended use, quantities on hand, and to complete a lab safety assessment.

DHHS/USDA SELECT AGENTS LIST
(March 18, 2005- Final rule)

DHHS NON-OVERLAP SELECT AGENTS & TOXINS	
<p>Cercopithecine herpes virus 1 (Herpes B Virus) Coccidioides posadasii Crimean-Congo haemorrhagic fever virus Ebola viruses Lassa fever virus Marburg virus Monkeypox virus Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments <i>Rickettsia prowazekii</i> <i>Rickettsia rickettsii</i> South American Haemorrhagic Fever viruses (Junin, Machupo, Sabia, Flexal, Guanarito)</p> <p>Tick-borne encephalitis complex (flavi) viruses (Central European tick-borne encephalitis, Far Eastern Tick-borne encephalitis, Russian spring and summer encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic fever)</p>	<p>Variola major virus (Smallpox virus) Variola minor virus (Alastrim) <i>Yersinia pestis</i></p> <p>Abrin Conotoxins Diacetoxyscirpenol Ricin Saxitoxin Shiga-like ribosome-inactivating proteins Tetrodotoxin</p>
OVERLAP SELECT AGENTS AND TOXINS	
<p><i>Bacillus anthracis</i> Botulinum neurotoxin producing species of <i>Clostridium</i> <i>Brucella abortus</i> <i>Brucella melitensis</i> <i>Brucella suis</i> <i>Burkholderia mallei</i> (formerly <i>Pseudomonas mallei</i>) <i>Burkholderia pseudomallei</i> (formerly <i>Pseudomonas pseudomallei</i>) <i>Coccidioides immitis</i> <i>Coxiella burnetii</i></p>	<p>Eastern equine encephalitis virus <i>Francisella tularensis</i> Hendra virus Nipah virus Rift Valley fever virus Venezuelan equine encephalitis virus</p> <p>Botulinum neurotoxin <i>Clostridium perfringens</i> epsilon toxin Shigatoxin Staphylococcal enterotoxin T-2 toxin</p>
USDA NON-OVERLAP SELECT AGENTS AND TOXINS	
<p>African horse sickness virus African swine fever virus Akabane virus Avian influenza virus (highly pathogenic) Bluetongue virus (exotic) Bovine spongiform encephalopathy agent Camel pox virus Classical swine fever virus <i>Cowdria ruminantium</i> (Heartwater) Foot and mouth disease virus Goat pox virus</p>	<p>Japanese encephalitis virus Lumpy skin disease virus Malignant catarrhal fever virus (Alcelaphine herpes virus type 1) Menangle virus <i>Mycoplasma capricolum</i>/M.F38/M. <i>mycoides capri</i> <i>Mycoplasma mycoides mycoides</i> Newcastle disease virus (velogenic) Peste Des Petits Ruminants virus Rinderpest virus Sheep pox virus Swine vesicular disease virus Vesicular stomatitis virus (exotic)</p>
LISTED PLANT PATHOGENS	
<p><i>Candidatus</i> Liberobacter africanus <i>Candidatus</i> Liberobacter asiaticus <i>Peronosclerospora philippinensis</i></p>	<p><i>Ralstonia solanacearum</i> race 3, biovar 2 <i>Sclerophthora rayssiae</i> var. <i>zeae</i> <i>Synchytrium endobioticum</i> <i>Xanthomonas oryzae</i> pv. <i>oryzicola</i> <i>Xylella fastidiosa</i> (citrus variegated chlorosis strain)</p>
<p><i>Note: De minimis quantity exemptions may be applied to many of the listed toxins. Contact the ORCBS at 355-0153 for further information if needed.</i></p>	

MIOSHA's Bloodborne Infectious Diseases Standard

This regulation is designed to minimize employee exposure risk of bloodborne pathogens that are associated with handling human blood & human-derived materials (including cells).

Any employee that will be working with human blood or other potentially infectious body fluids, unfixed tissue/organs other than intact skin, cell or tissue cultures, organ cultures, culture medium or other solutions that may contain bloodborne pathogens, or blood from experimental animals infected with bloodborne pathogens, must be included in MSU's Bloodborne Pathogens (BBP) Exposure Control Program. This program requires attending an initial training class that is held at the ORCBS and completing annual bloodborne pathogens refresher training. Initial training must be completed at the time of initial assignment to their duties that put them at risk of exposure to potentially infectious materials.

Employees included in the BBP Exposure Control Program must also be offered hepatitis B vaccination at no cost within ten days of assignment to their duties that put them at risk of exposure to potentially infectious materials.

For more information on the BBP requirements, contact Patti Pawski, Biosafety Industrial Hygienist at 432-8044 or email at pawski@msu.edu.

Impact of non-compliance:

- Increased risk of occupationally-acquired infections,
- Possible citation under Michigan Occupational, Safety & Health Administration (MIOSHA) Bloodborne Infectious Diseases Standard,
- May impact ability to purchase biological materials (ATCC, etc.),
- May cause delays in project approval by institutional review committees (IACUC, UCRIHS, IBC).

Infectious Agents

All work involving the use of agents infectious to humans should be conducted in accordance with the MSU Biosafety Manual. This manual is based on CDC's Biosafety in Microbiological and Biomedical Laboratories (BMBL), which outlines containment requirements (i.e. biosafety levels) for the safe use of infectious agents in both laboratory and animal research.

When research involves the use of cultures or samples that contain microorganisms that are potentially infectious to humans, biosafety level 2 (BSL-2) practices and facilities are required as a minimum. In order to assist the researcher with meeting BSL-2 requirements, the ORCBS offers a biosafety training course intended for all research personnel conducting work at this level. Additionally, the ORCBS Biosafety Staff will conduct a BSL-2 inspection to further aid the researcher in achieving BSL-2 requirements.

Impact of non-compliance:

- Increased risk of occupationally-acquired infections associated with research,
- May cause delays in project approval by institutional review committees (IACUC, UCRIHS, IBC),
- May impact ability to purchase or receive certain biological materials.

For further information regarding the use of infectious agents in research, please contact Jamie Willard, Biosafety Officer at 353-1877 or email at cherry@msu.edu.

Diagnostic Specimen & Infectious Substance Shipping

Transportation of biological materials is an activity that affects all research and diagnostic service entities. In some instances, these materials may be regulated for transportation and will require specific packaging, labeling and documentation. Additionally, the shipper must have documented training relative to his or her tasks associated with the shipment. This is the case for shipment of diagnostic specimens (from humans or animals), cultures of infectious substances (infectious to humans and/or animals), genetically modified organisms and any biological materials shipped on dry ice. In light of recent current events, there is an increased level of surveillance on the part of federal and international authorities for all hazardous materials/dangerous goods shipments that may include diagnostic specimens and infectious substances. As a shipper, it is essential to assure that materials are properly classified and that all applicable regulatory provisions for shipment are met.

The ORCBS offers training and consultation for campus personnel who plan to ship biological materials including: diagnostic specimens, infectious substances, genetically modified organisms, and biological materials on dry ice.

Impact of non-compliance:

- Increased risk of material release during the shipping process,
- May result in refusal or return of packages during the shipping process. This could be critical if materials are temperature sensitive.
- May result in fines from the Federal Aviation Administration (FAA).

Preparing to Ship Biological Materials:

Before you package and ship materials to an off campus destination there are several items that should be taken care of. These paperwork requirements can take several weeks to complete, therefore you should prepare well in advance for them.

1. Material Transfer Agreements

The Office of Intellectual Property requires that a Material Transfer Agreement be completed for materials entering or leaving campus. Before you send your shipment it is important that you contact the Office of Intellectual Property to ensure that the appropriate agreements are completed and processed.

You can contact the Office of Intellectual Property at 355-2186, or you can view their website at <http://www.oip.msu.edu>.

2. Export Controls and Trade Sanctions

Export controls and trade sanctions are regulatory areas that may apply to you, depending on your activity. Exports are any items (commodities, software, technology, select biological agents) sent from the United States to a foreign destination.

Export control laws may apply when one or more of the following concerns pertain to your research project:

- It has actual or potential military applications, including dual use items (i.e., commercial items with potential military application)
- The destination country, organization, or individual is restricted by federal law
- The declared or suspected end use or the end user of the export compromises national security
- Economic protection issues are associated with the destination country

If you have questions about whether there are export controls issues associated with your activity, contact Ronald Russell, Director, Office of Export Controls and Trade Sanctions (432-4500) or view the MSU Export Controls Web Site:

<http://www.msu.edu/unit/vprgs/expregs/overview.htm>

3. Permits

The CDC, USDA, U.S. Fish and Wildlife Service and Department of Commerce require permits for shipping certain etiological agents and other materials.

FAQ: Can I take my materials on the airplane with me (either in carried-on or checked baggage)?

The answer to this question is, it depends. It depends on the materials that you wish to take and if you have the proper paperwork in place. You **CANNOT** carry on or check biological materials if any of the following apply:

- The materials are classified as “dangerous goods;”
- Carriage of the materials is against rules established by the Transportation Security Administration (TSA);
- You do not have a completed material transfer agreement in place for the materials;
- Transport of the materials does not comply with export control and trade sanctions regulations; or
- Transport of the materials does not comply with Department of Transportation regulations.

For additional information refer to:

<http://www.msu.edu/~rohler/CMO%20Memo%20Sent%2010-20-06.pdf>

When in doubt, PLEASE ASK!

For more information on biological materials shipping requirements, please contact Jamie Willard (353-1877), Stephanie Smith-Edwards (355-1283) or Amber Bitters (432-5262).