

# 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](http://www.biosafety.msu.edu)), or contact the ORCBS Biosafety Staff at 353-1877 or 432-5262.*

## **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](mailto: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 (AUCAUC, UCRIHS, IBC),
- May result in loss of NIH funds for MSU.

### **MSU Office of Radiation, Chemical & Biological Safety (ORCBS) Biosafety Resources**

**Dr. Jamie Sue Willard**  
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## **DHHS/USDA Select Agent 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](mailto: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 agent 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 agent 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)  Cimean-Congo haemorrhagic fever virus  Coccidioides posadasii  Ebola viruses  Lassa fever virus  Marburg virus  Monkeypox virus  <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>  <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 353-1877 or 432-5262 for further information.</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 the completion of an initial training class offered through 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](mailto: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 (AUCAUC, UCRIHS, IBC).

## ***Regulations Associated With The Use Of 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 (AUCAUC, 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 Dr. Jamie Sue Willard, Biosafety Officer at 353-1877 ([cherryme@msu.edu](mailto:cherryme@msu.edu)) or Amber Bitters, Biological Industrial Hygienist at 432-5262 ([bitters1@msu.edu](mailto:bitters1@msu.edu)).

## ***New Diagnostic Specimen & Infectious Substance Shipping Policy at MSU***

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) and cultures of infectious substances (infectious to humans and/or animals). 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.

### **New Shipping Policy:**

Michigan State University has changed its policy on the shipment of biological materials. Unless you ship frequently (i.e., once a month or more), you must contact the Biosafety Team at the ORCBS each time you need to send biological materials and we will properly package your shipment for you. This change is a result of the continuously changing regulations and the liabilities and fines associated with non-compliance. The International Air Transportation Authority has issued several changes, effective January 1, 2005, regarding the shipment of diagnostic specimens, infectious substances and genetically modified microorganisms.

All MSU personnel wishing to ship biological materials with or without dry ice must initially contact the ORCBS Biosafety Team for assistance. If you are part of a group that ships infrequently we will package your shipment and prepare the paperwork for you. If you are part of a group that ships frequently (i.e., once a month or more) we will arrange for you to receive required training on the regulatory changes as soon as possible. The training is offered through a CD (Saf-T-Pak), which you can view in your own office or laboratory at your convenience. Please contact Amber Bitters (432-5262) or Dr. Jamie Sue Willard (353-1877) to schedule your CD training.

### **Reminder!**

- All biological materials must have a completed material transfer agreement before shipment. Contact the Office of Intellectual Property (355-2186 or online at <http://www.msu.edu/unit/oip/brochuresandforms.html>) for details.
- Shipments involving chemicals or materials on dry ice (other than biological materials) must be shipped through MSU Stores care of Nathan Maher.

### **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).

**For Further Assistance:**

Please contact Dr. Jamie Sue Willard (353-1877), Stephanie Smith-Edwards (355-1283) or Amber Bitters (432-5262).

## ***Biohazardous/Medical Waste Regulations***

At Michigan State University, the term biohazardous (medical waste) waste is used to describe waste that may include blood, infectious agents, toxins or recombinant DNA materials. Several regulations, guidelines and policies define what encompasses regulated biohazardous waste at MSU. The **Biohazardous Waste Management Plan** was developed to assist MSU personnel with defining, handling and disposing of biohazardous waste.

Biohazardous waste at MSU is regulated by the Michigan Medical Waste Regulatory Act (MMWRA), the Michigan Occupational Safety and Health Administration (MIOSHA) Bloodborne Infectious Diseases Standard and the NIH Guidelines for Research Involving Recombinant DNA Molecules. In short the following categories of waste are considered biohazardous and must be disposed of properly.

- Cultures and stocks of infectious agents and associated biologicals, including laboratory wastes, discarded live and attenuated vaccines, culture dishes and related devices;
- Liquid human and animal waste, including blood and blood products and body fluids (not including urine). This includes items that are caked with blood and are capable of releasing blood during handling and items that will release blood or other potentially infectious body fluids in a liquid or semi-liquid state if compressed;
- Sharps, which means needles, syringes (with or without needles), scalpels and intravenous tubing with needles attached. Sharps also include any contaminated object that can penetrate the skin;
- Pathological waste, which means human organs, tissues, body parts other than teeth, products of conception and fluids removed by trauma or during surgery or autopsy or other medical procedure, and not chemically fixed (i.e. formalin);
- Contaminated wastes from animals that have been exposed to agents infectious to humans, these being primarily research animals.

Any personnel who generate medical/biohazardous waste must be trained. Please contact the MSU Biosafety Team at 353-1877 or 432-5262 for assistance.