

## Researcher Guidance Document

A number of regulatory requirements apply to the procurement use and disposal of hazardous chemicals, biological & radioactive materials, select agents, hazardous wastes, and the import/export of certain materials and technology. Before beginning any new research involving humans, animals, plants, recombinant DNA or biohazards, institutional approval by one or more university committees may be required. Environmental Health & Safety (EHS), Office of Responsible Research Practices (ORRP), and Office of Research Compliance (ORC) provide programs and services to help you meet requirements associated with your research.

### **New Researcher Consultation Services**

Research Safety staff provide consultation services to new principal investigators, existing laboratories and staff members throughout the university community. Our consultation services encompass a broad range of topics which include laboratory safety, new laboratory set up, assistance with biosafety protocols and procedures, risk assessments, laboratory waste management and comprehensive knowledge of Federal and State Regulations surrounding laboratories. To inquire about how you can request a consultation, visit our [service request page](#) or contact your Environmental Safety Representative.

Service Request Form Choose:

**Service Area** (Research Safety/ BioSafety)

**Select a Service:** (New Researcher Consultation)



RESEARCH	REGULATIONS & REQUIREMENTS	RESOURCES & INFORMATION
<b>Hazardous chemicals</b>		
Procurement, Distribution & Transportation	<p>Procurement process (limit purchase amount, COI thresholds)</p> <p>Certain materials, such as controlled substances and select agent toxins, must not be distributed to other investigators without prior approval; if routine laboratory chemicals are transferred between investigators, the transfer must also occur in the online chemical inventory (EHSA)</p> <p>Transportation of chemicals must be done safely and in proper secondary containment. Proper spill clean-up supplies must be available. Transportation of chemicals to off-campus locations must be done by an approved vendor.</p>	<p>Contact the EHS Chemical Security Program for more information.</p> <p>See the <a href="#">OSU Chemical Hygiene Plan</a>, Section 6.3 or contact EHS for additional information.</p> <p>See the <a href="#">OSU Chemical Hygiene Plan</a>, Section 6.4 or contact EHS for additional information.</p>
Use	<p><b>OSHA's Laboratory Standard 1910.1450</b></p> <p>Develop a lab specific Chemical Hygiene Plan (CHP) and ensure that personnel understand and follow the plan.</p> <p>All lab personnel, including the Principal Investigator must complete Lab Standard Training before beginning work.</p>	<p><a href="#">Chemical Hygiene Plan application</a> assists you in development of your laboratory CHP.</p> <p>Lab Standard Training is available online or classroom. Contact EHS for classroom for dates and times.</p>
	<p><b>Department of Homeland Security (DHS) Chemical Facility Anti-Terrorism Standards (CFATS)</b></p> <p>Maintain a hazardous chemical inventory using the Environmental Health and Safety Assistant (EHS Assist) chemical inventory system.</p> <p>Update changes to Chemicals of Interest within 30 days and audit inventory on an annual basis.</p> <p>For assistance with the EHSA system contact Research Safety.</p>	<p>Contact EHS for more information.</p> <p><b>Note:</b> EHS reports chemicals of interest (COI) at or above the threshold quantities to DHS, based on the information provided in the EHS Assist system. For this reason it is important to keep chemical inventories current.</p>
Hazardous Chemical Waste	<p>Package, store and dispose of hazardous chemical wastes in accordance with applicable OEPA and RCRA regulations.</p>	<p>EHS provides waste disposal and consultation services to OSU researchers. All requests for disposal pickups and consultation services should be submitted online via the <a href="#">EHS Online Waste Disposal Request</a>. For further details on waste disposal, contact the EHS Environmental Affairs Program.</p> <p>See the <a href="#">Chemical Waste Management Reference Guide</a> for additional Information.</p>

RESEARCH	REGULATIONS & REQUIREMENTS	RESOURCES & INFORMATION
<b><i>Biological Materials</i></b>		
Infectious Waste	Package, store & dispose of infectious waste in accordance with all applicable OEPA regulations	EHS provides waste disposal and consultation services to OSU researchers. All requests for disposal pickups and consultation services should be submitted online via the <a href="#">EHS Online Waste Disposal Request</a> . For further details on waste disposal, contact the EHS Environmental Affairs Program.
Biosafety cabinets (BSC)	<p>Train all lab personnel on the proper use of BSC.</p> <p>Ensure that BSCs are certified to NSF/ANSI Standard 49 by a qualified contractor at time of installation, annually thereafter, when moved, and after major repairs.</p> <p>BSCs must be gas decontaminated prior to moving and before any repair that entails work in a potentially contaminated plenum (i.e. HEPA filter change, motor change)</p>	EHS offers Online Biosafety Cabinet Training
Microorganisms considered pathogenic to humans, plants, or animals (based on wild-type organism)	<p>Submit protocol application to the Institutional Biosafety Committee.</p> <p>All lab personnel performing Biosafety Level 2 (BSL-2) research, including the Principal Investigator must complete BSL- 2, Bloodborne Pathogens Initial training before beginning work.</p>	<p>Protocol application must be submitted using the e-protocol system. Visit the <a href="#">IBC eProtocol web page</a> for further information and instructions on how to submit a research protocol.</p> <p>Online training resources are available through the EHS website.</p>
Human Subjects	Obtain institutional approval from the Institutional Review Board (IRB).	Visit the <a href="#">IRB website</a> for more information on human subject's research requirements.
Human gene transfer research	<p>Obtain institutional approval of your research from the appropriate Institutional Review Board (IRB).</p> <p>For human gene transfer research, submit a protocol application to the Institutional Biosafety Committee. IBC approval is required before the IRB will approve the research.</p>	<p>The <a href="#">IRB Investigator Guidance web page</a> may help you determine the appropriate review process for your research.</p> <p>Protocol application must be submitted using the e-protocol system. Visit the <a href="#">IBC eProtocol web page</a> for further information and instructions on how to submit a research protocol.</p>
Importing or exporting any of the following from/to another state or another country: human infectious substances; biological materials; hosts, vectors, animals; materials pathogenic to livestock/ poultry; plant pathogens; arthropod plant pests; genetically engineered organisms; select agents; technical data, technology, or commodities (including technical information to foreign persons).	If applicable, obtain import, export, and/or transfer permits or licenses.	<p>Refer to <a href="#">Import, Export and Transfer of Biological Materials Guide</a> for additional information on the import, export, and transfer permits and licenses.</p> <p>Refer to the <a href="#">Office of Research Compliance Export Control web page</a> for information on compliance with export control regulations.</p> <p>Refer to the <a href="#">University Lab Animal Resources web page</a> for more information on transferring animals</p>

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<b>Biological Materials</b>		
<p>Use of human blood or other potentially infectious materials, including:</p> <ul style="list-style-type: none"> <li>♦ Human organs, unfixed tissue (other than intact skin),</li> <li>♦ Human cell lines or primary cell cultures <ul style="list-style-type: none"> <li>♦ Human body fluids</li> </ul> </li> <li>♦ HIV – containing cell or tissue cultures, organ cultures, and HIV- or HBV- containing culture medium or solutions</li> <li>♦ Blood, organs, or tissue from experimental animals infected with HIV or HBV</li> </ul>	<p>The Occupational Safety &amp; Health Administration (OSHA) Bloodborne Pathogens Standard applies to your research. All employees who could be reasonably expected to have potential occupational exposures to blood and other potentially infectious materials must be offered Hepatitis B vaccination and must complete Bloodborne Pathogens Training prior to starting work. Training is required at least annually thereafter.</p> <p>Maintain an Exposure Control Plan (ECP) and ensure that personnel understand and follow the plan. The OSU ECP can be found at the EHS Biosafety Web Page. Complete Appendix A for your laboratory. This ECP must be revised annually, if necessary, and reviewed by all lab staff. Ensure that all personnel performing Biosafety Level 2 (BSL-2) research complete BSL- 2 training.</p>	<p>Online training and further details are available on the EHS Bloodborne Pathogens Web Page.</p> <p>EHS offers Online BSL-2 Training</p>
	<p>Submit a protocol application to the Institutional Biosafety Committee (IBC). Human source material, including established cell lines must be registered with the IBC even if they are the ONLY biohazard present in the lab.</p>	<p>Protocol application must be submitted using the e-protocol system. Visit the <a href="#">IBC eProtocol web page</a> for further information and instructions on how to submit a research protocol.</p>
<p>Creating recombinant DNA/ RNA constructs (vector plus gene); or inserting recombinant DNA/RNA constructs into cell lines/tissue cultures, whole animals, humans, or plants</p>	<p>Either register your “exempt” research or submit a protocol application to the Institutional Biosafety Committee. Ensure that all personnel performing Biosafety Level 2 (BSL-2) research complete Online BSL-2 Training.</p>	<p>Protocol application must be submitted using the e-protocol system. Visit the <a href="#">IBC eProtocol web page</a> for further information and instructions on how to submit a research protocol.</p> <p>The <a href="#">IBC Investigator Guidance web page</a> may help you determine the appropriate review process for your research.</p>
<p>Exotic (not known to occur in Ohio) plants or plant pests</p>	<p>When applicable, meet requirements of the USDA Animal and Plant Health Inspection Service (APHIS).</p>	<p>Visit <a href="http://aphis.usda.gov">aphis.usda.gov</a> for further details</p>
<p>Use of animals or primary animal tissues</p>	<p>Submit a protocol application to the Institutional Animal Care and Use Committee.</p> <p>Transgenic animals must also be registered with the Institutional Biosafety Committee prior to IACUC approval of research.</p>	<p>See the <a href="#">IACUC eProtocol web page</a> for further information and instructions on how to submit an IACUC protocol.</p> <p>Visit the <a href="#">IBC eProtocol Web Page</a> for further information and instructions on how to submit a research protocol.</p>
<p>Use or possession of select agents and toxins as defined by the US Department of Agriculture and/or Centers for Disease Control and Prevention</p>	<p>Possession, use and transfers of select agents must be in accordance with federal mandates. Prior approval from the Responsible Official (RO) or Alternate RO is required to possess, use, or transfer select agents or quantities of select toxins above the permissible toxin amounts to/from OSU.</p>	<p>Contact the Responsible Official or Alternate Responsible Official at (614) 292-1284 for information on regulatory and institutional requirements.</p>

RESEARCH	REGULATIONS & REQUIREMENTS	RESOURCES & INFORMATION
<b><i>Radiological Materials</i></b>		
Use of Radioactive materials	Submit a protocol to the University Radiation Safety Committee.	Refer to the <a href="#">EHS Radiation Safety web page</a> for additional information and to download application forms or phone EHS at (614) 292-1284.
Radioactive Waste	Package, store & dispose of radioactive waste in accordance with Ohio Department of Health Regulations	See the Radioactive Waste Management Handbook or call the Radiation Safety Program for additional information.
Use of Class III or IV Lasers	Follow American National Standard for Safe Use of Lasers (ANSI Z136.1-2007) Comply with the OSHA Non-Ionizing Radiation Standard Develop lab-specific SOPs	Contact EHS at (614) 292-1284 to register your laser(s) and obtain additional information on Laser Safety. See the <a href="#">EHS Laser Safety Program page</a> for more information. EHS offers Online Laser Safety Training.
Use of X-Ray Machines	Comply with applicable Ohio Department of Health regulations.	See the <a href="#">EHS Non-medical X-ray Devices web page</a> or contact Radiation Safety at (614) 292-1284 for more information.

RESEARCH:	REGULATIONS & REQUIREMENTS	RESOURCES & INFORMATION:
<b><i>Other Materials &amp; Requirements</i></b>		
Use or possession of drugs or controlled substances that have potential for abuse (e.g., barbitol, chloral hydrate, opiates, and methamphetamine)	Controlled substances must be used under the direct auspices of a person licensed by the Drug Enforcement Administration (DEA) and the State Board of Pharmacy.  Each researcher using controlled substances is responsible for ensuring compliance with appropriate state and federal requirements and Ohio State University policy. In some areas of campus, PIs hold individual licenses for the use of controlled substances in research. The College of Medicine also provides a process for researchers to use controlled substances for research under a single license located at the Ohio State Medical Center Department of Pharmacy.  Note: Expired drugs cannot be used in animals.	Contact the Ohio State Board of Pharmacy at (614) 466-4143 for information on license requirements. Refer to Drug Enforcement Administration Web Page for additional information. Note: PIs within the College of Medicine using controlled substances may go to the OSU Medical Center Department of Pharmacy to make arrangements for procurement on their license at (614) 293-8470.  See the <a href="#">Ohio State University Policy on Investigator Use of Controlled Substances in Research</a>
Researchers resigning, retiring, or leaving the University	Segregate and inventory all chemicals.  Arrange for disposal of all biological, chemical, and radiological materials in accordance with applicable regulations and EHS policy.  Decontaminate all work surfaces and equipment. Leave laboratory clean and ready for next occupant.  Notify the appropriate ORRP staff to terminate any active protocols or transfer the responsibility to another investigator.	Contact the EHS Research Safety Program at (614) 292-1284 to arrange for a final walk-through of your laboratory. Visit <a href="http://www.ehs.osu.edu">http://www.ehs.osu.edu</a> for additional information, to request waste disposal services, or to request pick up of usable chemicals for re-distribution. Contact the ORRP to notify the appropriate committee(s).
Mercury Thermometer Exchange Program	Ohio State University is in a position to reduce or eliminate mercury prior to the implementation of federal mandates and supports the USEPA push to reduce mercury waste.	The EHS provides a one-for-one exchange of mercury thermometers for non-mercury thermometers. <a href="#">Mercury Thermometer Exchange Request</a>

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<b>Other Materials &amp; Requirements</b>		
All researchers need to be familiar with the Building Emergency Action Plan (BEAP) previously known as EOEP for their department, as well as develop lab-specific responses to emergencies.	Become familiar with your BEAP so you are prepared for building emergencies. Develop and train staff on appropriate clean-up procedures for biohazard, chemical, and/ or radiological spills.	Contact your building coordinator or departmental safety representative to access a copy of the BEAP. Contact EHS at (614) 292-1284 for additional information on building emergency planning and to arrange training. Online BEAP Training is available.
Shipping hazardous materials to other locations	Comply with hazardous material transportation regulations. Personnel who package and ship hazardous materials must complete appropriate training to properly classify, identify, mark, label, pack, and handle shipments, as well as complete required shipping documentation. DOT Hazardous Materials training is required for individuals who ship hazardous materials. International shipments and shipments through carriers who require compliance with International Air Transportation Association (IATA) must be in accordance with IATA Dangerous Goods Regulations. IATA and/or DOT training is required for individuals who ship hazardous materials.	Refer to the DOT Hazardous Materials regulations. Refer to the <a href="#">IATA web page</a> for details regarding Dangerous Goods Regulations. Dangerous Goods Training for shipping biological/ infectious substances is available online at the no charge at the <a href="#">Mayo Clinic Medical Laboratories web page</a> . IATA training is available for a fee from: <a href="#">Safex</a> offers an IATA training course for persons shipping hazardous materials. DOT training CDs can be purchased from the USDOT, <a href="#">Office of Hazardous Materials Safety web page</a> .
	OSHA's Hazard Communication Standard requires hazardous chemicals to be provided with a MSDS. Develop and maintain MSDS for synthesized chemicals. MSDS shall be included in shipments of synthesized chemicals to other entities.	Refer to <a href="#">OSHA Hazard Communication Standard 29 CFR 1910.1200 (g)</a> or contact EHS at (614) 292-1284 for details.

EMERGENCY CONTACT INFORMATION	
Chemical or Biological Spills	Contact EHS: (614) 292-1284 After hours, contact OSU Police: (614) 292-2121
Radiological Spills	Contact EHS: (614) 292-1284 After hours cell: (614) 561-7969
Occupational Exposures	Contact/report to Employee Health Services: (614) 293-8146 For medical emergencies after hours, contact/report to OSUMC Emergency Department: (614) 293-8333
Security Issues Medical Emergencies Fires	Dial 911 from a campus phone, or dial (614) 292-2525 from a cell phone