



# PI Guide to Protocol Review and Regulatory Requirements

If your research involves humans, animals, plants, recombinant DNA or biohazards, it may require institutional approval by one or more university committees. Regulatory requirements apply to the use of hazardous and radioactive materials; select agents; disposal of hazardous, infectious and radioactive wastes; and import/export of certain materials and technology. The Office of 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.

FOR RESEARCH THAT INVOLVES:	YOU NEED TO:	FOR MORE INFORMATION:
Use of hazardous chemicals	<p>Comply with OSHA's Laboratory Standard.</p> <p>Develop a chemical hygiene plan (CHP) and ensure that personnel understand and follow the CHP.</p> <p>Ensure that all lab personnel complete Lab Standard Training.</p>	<p>Refer to the <a href="#">EHS Chemical Hygiene Plan Web Page</a> for further details and to access a template, which will facilitate you in developing a CHP for your lab(s).</p> <p><a href="#">Online Lab Standard Training</a> is available, or contact EHS at (614) 292-1284 for the classroom training schedule.</p>
	<p>Comply with the Department of Homeland Security (DHS) Chemical Facility Anti-Terrorism Standards (CFATS).</p> <p>Enter and maintain an inventory of hazardous chemicals using the <a href="#">EHS Assistant</a> web-based chemical inventory system, which is an online limited access database. The online database and instructions can be accessed at <a href="#">EHS Web Page</a>.</p> <p>Update changes to inventories of <a href="#">DHS Chemicals of Interest</a> within 30 days in EHS Assistant.</p> <p>Review and update chemical inventory in EHS Assistant on at least an annual basis.</p>	<p>Note: Based upon the chemical inventories in the EHS Assistant web-based chemical inventory system, EHS will report to DHS when the university possesses chemicals of interest are at or above the standard threshold quantity. For this reason, it is important that all OSU faculty and staff maintain up-to-date chemical inventories in EHS Assistant.</p> <p>When researchers possess COI at or above the standard threshold quantities, EHS will facilitate researchers with CFATS compliance. For additional information, visit the <a href="#">EHS Chemical Security Web Page</a> or contact EHS at (614) 292-1284.</p>
Generation of hazardous, infectious or radioactive waste	Dispose of hazardous, infectious and/or radioactive wastes in accordance with applicable state and federal regulations.	EHS provides waste disposal and consultation services to OSU researchers. For further details on waste disposal, contact EHS at (614) 292-1284, visit the <a href="#">EHS Web Page</a> , or take the <a href="#">Online Infectious Waste Training</a> .
Use of <a href="#">Radioactive materials</a>	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.

FOR RESEARCH THAT INVOLVES:	YOU NEED TO:	FOR MORE INFORMATION:
Use of Class III or IV Lasers	<p>Follow American National Standard for Safe Use of Lasers (ANSI Z136.1-2007)</p> <p>Comply with the OSHA Non-Ionizing Radiation Standard</p> <p>Develop lab-specific SOPs</p>	<p>Contact EHS at (614) 292-1284 to register your laser(s) and obtain additional information on Laser Safety.</p> <p>EHS offers <a href="#">Online Laser Safety Training</a>.</p>
Use of X-Ray Machines	Comply with applicable Ohio Department of Health regulations.	Contact Radiation Safety at (614) 292-1284
Use of microorganisms that are pathogenic to humans, plants, or animals (based on wild-type organism)	<p>Submit a protocol application to the Institutional Biosafety Committee.</p> <p>Ensure that all personnel performing Biosafety Level 2 (BSL-2) research complete BSL- 2 training.</p>	<p>Visit the <a href="#">IBC Web Page</a> for further information and instructions on how to submit a research protocol.</p> <p>EHS offers <a href="#">Online BSL-2 Training</a></p>
Use of a biosafety cabinet (BSC)	<p>Train all lab personnel on the proper use of BSC.</p> <p>Ensure that BSCs are certified by a qualified contractor at time of installation, annually thereafter, when moved, and after major repairs.</p>	EHS offers <a href="#">Online Biosafety Cabinet Training</a>
<a href="#">Human subjects</a>	Obtain institutional approval of your research from the appropriate Institutional Review Board (IRB).	The <a href="#">IRB Investigator Guidance Web Page</a> may help you determine the appropriate review process for your research.
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>Visit the <a href="#">IBC Web Page</a> for further information and instructions on how to submit a research protocol.</p>
Exotic (not known to occur in Ohio) <a href="#">plants or plant pests</a>	When applicable, meet requirements of the USDA Animal and Plant Health Inspection Service (APHIS).	Visit <a href="http://www.APHIS.USDA.gov">www.APHIS.USDA.gov</a> for further details
Use of animals or primary animal tissues	<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 Web Page</a> for further information and instructions on how to submit an IACUC protocol.</p> <p>Visit the <a href="#">IBC Web Page</a> for further information and instructions on how to submit a research protocol.</p>

FOR RESEARCH THAT INVOLVES:	YOU NEED TO:	FOR MORE INFORMATION:
<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</li> <li>• Human body fluids</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 <a href="#">EHS Biosafety Web Page</a>. Complete Appendix A for your laboratory. This ECP must be revised annually, if necessary, and reviewed by all lab staff.</p> <p>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 <a href="#">EHS Bloodborne Pathogens Web Page</a>.</p> <p>EHS offers <a href="#">Online BSL-2 Training</a></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>Visit the <a href="#">IBC Web Page</a> to 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.</p> <p>Ensure that all personnel performing Biosafety Level 2 (BSL-2) research complete <a href="#">Online BSL-2 Training</a>.</p>	<p>Visit the <a href="#">IBC 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>Use or possession of <a href="#">select agents and toxins</a> 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 <a href="#">permissible toxin amounts</a> 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> <p>Additional information about select agents is accessible on the <a href="#">EHS Select Agent Web Page</a>.</p>

<b>FOR RESEARCH THAT INVOLVES:</b>	<b>YOU NEED TO:</b>	<b>FOR MORE INFORMATION:</b>
<p>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.</p>	<p>Become familiar with your BEAP so you are prepared for building emergencies.</p> <p>Develop and train staff on appropriate clean-up procedures for biohazard, chemical, and/ or radiological spills.</p>	<p>Contact your building coordinator or departmental safety representative to access a copy of the BEAP.</p> <p>Contact EHS at (614) 292-1284 for additional information on building emergency planning and to arrange training. <a href="#">Online BEAP Training</a> is available.</p>
<p>Use or possession of drugs or controlled substances that have potential for abuse (e.g., barbitol, chloral hydrate, opiates, and methamphetamine)</p>	<p>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.</p> <p>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.</p> <p>Note: Expired drugs cannot be used in animals.</p>	<p>Contact the <a href="#">Ohio State Board of Pharmacy</a> at (614) 466-4143 for information on license requirements.</p> <p>Refer to <a href="#">Drug Enforcement Administration Web Page</a> for additional information.</p> <p>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.</p> <p>See the <a href="#">Ohio State University Interim Policy on Investigator Use of Controlled Substances in Research</a> at the <a href="#">Office of Research Compliance Web Page</a>.</p>
<p>Importing or exporting any of the following from/to another state or another country:</p> <ul style="list-style-type: none"> <li>• human infectious substances;</li> <li>• biological materials;</li> <li>• hosts, vectors, animals; materials pathogenic to livestock/ poultry;</li> <li>• plant pathogens;</li> <li>• arthropod plant pests;</li> <li>• genetically engineered organisms;</li> <li>• select agents;</li> <li>• technical data, technology, or commodities (including technical information to foreign persons).</li> </ul>	<p>If applicable, obtain import, export, and/or transfer permits or licenses.</p>	<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>

FOR RESEARCH THAT INVOLVES:	YOU NEED TO:	FOR MORE INFORMATION:
Shipping hazardous materials to other locations	<p>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.</p>	<p>Refer to the <a href="#">DOT Hazardous Materials regulations</a>. DOT training is available free of charge, on the <a href="#">EHS Online Training Web Page</a>.</p> <p>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></p> <p>IATA training is available for a fee from:</p> <ul style="list-style-type: none"> <li>• <a href="#">Safex</a> offers an IATA training course for persons shipping hazardous materials.</li> <li>• Training to ship infectious substances and/or biological materials in accordance with DOT and IATA may be purchased from <a href="#">Saf-T-Pak</a> (training is available via seminar, internet, and CD).</li> </ul>
	<p>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.</p>	<p>Refer to <a href="#">OSHA Hazard Communication Standard 29 CFR 1910.1200 (g)</a> or contact EHS at (614) 292-1284 for details.</p>
<p>Researchers resigning, retiring, or leaving the University</p>	<p>Segregate and inventory all chemicals.</p> <p>Arrange for disposal of all biological, chemical, and radiological materials in accordance with applicable regulations and EHS policy.</p> <p>Decontaminate all work surfaces and equipment. Leave laboratory clean and ready for next occupant.</p> <p>Notify the appropriate ORRP staff to terminate any active protocols or transfer the responsibility to another investigator.</p>	<p>Contact EHS at (614) 292-1284 or visit <a href="http://www.ehs.ohio-state.edu">www.ehs.ohio-state.edu</a> for additional information, to request waste disposal services, or to request pick up of usable chemicals for re-distribution.</p> <p>Contact the <a href="#">ORRP</a> to notify the appropriate committee(s).</p>
<div data-bbox="181 1686 376 1871" data-label="Image"> </div> <p><b>EHS encourages researchers to use the following programs to enhance sustainability efforts at OSU (please phone EHS at 614-292-1284 for more information on these programs):</b></p> <ul style="list-style-type: none"> <li>• Usable chemicals no longer needed in the laboratory can be submitted to the EHS Chemical Redistribution Program. Chemicals in the EHS Chemical Redistribution Program are available to OSU faculty and staff at no charge.</li> <li>• EHS will pick up and recycle universal waste (e.g., batteries, lamps, ballasts).</li> </ul>		



## EMERGENCY CONTACT INFORMATION

IN THE EVENT OF:	EMERGENCY CONTACT NUMBERS:
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 pager: (614) 240-0705
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

