Research Compliance at Ohio University

If you've recently submitted a proposal to a prospective sponsor that will require the use of human subjects, animals or hazardous materials, you need to be sure that the process to receive university approval to conduct research using those items has commenced. In a few cases, you may have already been required to complete this step as a condition of your application. Depending on what is proposed in your research, the timeframe for approval to use the above categories can range vastly. It is important to have your approvals in place before an award is made, because although the funds have arrived at OHIO, you will not be approved to spend until all the necessary documentation has been received by the Office of Research Compliance and subsequently shared with ORSP.

Office of Research Compliance

The Office of Research Compliance (ORC) is a unit of the Vice President for Research division that is responsible for ensuring overall compliance with applicable federal, state, and institutional policies with regard to research. The unit administers, supports, guides and oversees the work of various compliance committees to uphold ethical and regulatory standards and practices. The office manages research-related regulatory mandates including areas such as the Institutional Review Board (IRB) for human subjects research, the Institutional Animal Care and Use Committee (IACUC), research conflicts of interest and management of the fraud and misconduct process. In addition the animal care and facilities staff report to this office. Staff includes the Director for Research Compliance; Associate Director for Research Compliance (compliance); Associate Director for Research Compliance (animal facilities); the Assistant Director for Research Compliance (animal facilities); IRB Coordinator; IACUC Coordinator; and administrative assistant for the Compliance Office. Contact information for all of the above are located on the research compliance website, ***www.ohiou.edu/research/compliance.***

Institutional Review Board (IRB)

The Institutional Review Board for Human Subjects Research (IRB) is the committee at OHIO charged with assuring the protection of human subjects. This is done through education as well as a review and monitoring process to ensure that the research complies with applicable regulations. All research studies conducted by faculty, staff, or students that involve human subjects must be approved by the IRB before the project can begin. To assist in the determination of whether a project requires review, it is important to know two definitions:

research: **a systematic investigation, including research development, testing and evaluations, designed to contribute to generalizable knowledge.**

human subject: **a living individual about whom an investigator conducting research obtains 1) data through intervention or interaction with the individual OR 2) identifiable private information**

In the definition of research, the clause, "designed to contribute to generalizable knowledge" is the part that most often is used to determine if a project meets the definition of research, and thus requires IRB review. For example, a survey done by a university department to assess how satisfied users of that department are with services provided would not be considered research if the use of the survey data was internal, i.e. to determine how the department might improve its services. If that same department wanted to publish a paper using that survey data, claiming that it had an innovative departmental structure as well as services that other University departments might benefit from, then this survey distribution is crossing over into being "designed to contribute to generalizable knowledge" and would require IRB review. Intent to publish is one possible indication of intent to contribute to generalizable knowledge.

Examples of circumstances where the definition of human subject is not met, is with archival data of individuals who are now deceased, or biological specimens that are completely stripped of any identifying information and not coded in any way. Any person who has questions as to whether or not activities would require IRB oversight is encouraged to contact ORC for assistance in making the determination.

The use of discarded human tissue may require IRB approval. The level of review required will vary depending on the type of identifying information that is used. Should you have the need to use discareded human tissue as a part of your research please consult the IRB staff, and they will assist you in determining the level of review that is required.

Why IRB is important to research

Review is required by federal legislation and serves to protect both the human subject and the researcher. Researchers applying for internal or external funding are required to receive IRB approvals prior to receiving, and in some cases prior to applying for, that funding. Many publications will no longer accept manuscripts that do not have IRB approval. The IRB does not issue approvals retroactively so understanding the requirements and seeking the appropriate approvals prior to engaging in research is critical.

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IRB Committee

The IRB is currently appointed through Faculty Senate. The committee membership includes faculty members with expertise in the area of human research, administrators, non-affiliated community representation and physicians.   The IRB normally meets monthly and there is a submission deadline approximately two weeks ahead of each meeting for a protocol to be included on the agenda. Deadlines and meeting dates are posted on the compliance website, ***www.ohiou.edu/research/compliance,*** *for each quarter.*

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Approval Process

Once an activity has been determined to require IRB oversight, it is submitted to ORC via a Project Outline Form. Staff of the ORC will then review the proposal and determine what review level is required. In determining the review level, the risk to the participants must be assessed using the following definition:

minimal risk: **the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves that those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.**

The Project Outline Form can be found at:
http://www.ohiou.edu/research/compliance/irb_forms2002.html#forms

There are three review levels:

Exempt: For studies that are determined to be minimal risk and meet one of six defined categories in the federal regulations. Some general examples of exempt studies are: studies that examine the effectiveness of an instructional technique, anonymous surveys with adults (over the age of 18), or observation of public behavior. Exempt proposals are not sent to the IRB, but are processed in the Office of Research Compliance. Investigators may not declare their own project exempt. To obtain a letter of exemption, prior to beginning, investigators should submit a project outline form. The average turnaround is 1 – 2 weeks.

Expedited: For studies that are determined to be minimal risk and meet one of nine defined categories in the federal regulations. Expedited proposals are sent to a subcommittee of the IRB. The average turnaround for review is 2 – 3 weeks. For a complete list of exempt and expedited categories, consult the "Guidelines for Review of Research Involving Human Subjects" on the IRB forms website.

Full Committee: For studies that are determined to be greater than minimal risk or do not meet one or more of the categories for exempt or expedited studies. Full committee proposals must be reviewed in a convened meeting of the IRB. The IRB typically meets once per month. Meeting schedule and submission deadlines are posted on the Research Compliance website. The average turnaround is 3 – 4 weeks.

The use of certain classes of participants (prisoners, pregnant, women, children) require additional safeguards. Researchers proposing to conduct non-exempt research must complete training in the protection of human subjects. The training is a web-based module available on the Compliance website: ***http://www.ohiou.edu/research/compliance.***

Regardless of review level, a signed approval letter will be sent to all investigators of a research project. If the proposal was determined to be exempt, there is no expiration date, and no need to "renew" the approval. For non-exempt proposals, approval is good for a maximum period of twelve months. The expiration date is listed on the approval form. It is important to request a periodic review several weeks prior to expiration of the previous approval. Once a proposal approval has expired, all research related procedures must halt, except when doing so would jeopardize the welfare of human subjects. The approval remains in effect provided the study is conducted exactly as described in the application for review. Any additions or modifications to the project must be approved by the IRB (as an amendment) prior to implementation. Adverse or unanticipated events must be reported to the IRB promptly, within 5 working days of the occurrence.

Forms

All Compliance forms are available on the ORC website, ***www.ohiou.edu/research/compliance***.

Project Outline Form: This form is used to describe a research project. It is used for new submissions, regardless of review level.

Amendment Form: This form is used to request a modification to a previously approved proposal.

Periodic Review Form: This form is used to request a ‘renewal’ of a previously approved study.

Adverse Event Reporting Form: This form is used to report any undesirable or unintended injury or physical or emotional consequence to a human subject. Such report is required as soon as possible, and within 5 working days of the occurrence.

Assurances

The Office of Human Research Protections (OHRP), within the US Department of Health and Human Services, is the agency charged with overseeing human subjects research. OHIO has an OHRP-approved federal wide assurance of compliance with the HHS regulations (45 CFR 46) for the protection of human subjects. The assurance number is FWA00000095.

TIP!

The human subjects assurance identification for OHIO is FWA00000095.

The Institutional Animal Care and Use Committee (IACUC)

The Institutional Animal Care and Use Committee (IACUC) is the committee at OHIO charged with assuring the protection of animals used in research, teaching and testing. This is done through education and a review and monitoring process to ensure that the research complies with applicable regulations.

Why IACUC is important to research

Review is required by federal regulation and serves to protect both the animals being used as well as the persons conducting the research. All use of animals in research, teaching or testing by OHIO personnel requires IACUC review prior to start of work, whether funded or not. Investigators seeking external funding should determine at what stage approval is required by the agency to which they are applying. Some funding agencies require approval prior to submitting an application for funding; others require the approval prior to release of funding once awarded. Internal funding programs require approval prior to release of funds. Most publications will not accept manuscripts without documentation of IACUC approval for the work.

All use of animals in research, teaching or testing by OHIO personnel requires IACUC review prior to start of work whether funded or not.

IACUC Committee

The Vice President for Research, who also serves as the Institutional Official for animal research issues, appoints the IACUC. The committee includes expert representation from the disciplines using animals in research, a veterinarian and a non-affiliated community member. Deadlines and meeting dates for each quarter are posted on the compliance website, ***www.ohiou.edu/research/compliance.***

The IACUC normally meets monthly and there is a submission deadline approximately two weeks ahead of each meeting for a protocol to be included on the agenda.

Approval Process

All investigators must complete the animal care training program in order to receive approval to use animals in research, testing or teaching. OHIO uses a designated reviewer system for protocol review. Protocols, renewals and addenda are submitted to a centralized research compliance office for processing. Protocols for USDA covered species are approved for a maximum of 1 year. A maximum of 3 years is approved for other species. The IACUC may specify a shorter time period of approval. For both designated and full review, once the final outcome of the protocol review is completed the compliance office notifies the investigator of the outcome and the approval or denial of approval of the protocol.

The IACUC chair determines the method of review. In the case that a protocol or amendment is identified for designated review, a complete copy of the protocol is sent to the designated reviewers for review and all other members receive notification that the designated review is occurring. In practice, the full committee reviews most protocols, renewals and addenda. OHIO uses a “pre-review” system in which the reviewers submit issues raised during their initial review to the central IACUC office where they are compiled and sent to the investigator prior to the meeting. The investigator response, and a revision if submitted, is sent to the IACUC prior to the monthly meeting where the entire committee reviews it. At the meeting protocols may be called to a vote for approval where they either receive approval or have approval withheld. Protocols that have issues that are unresolved, or for which additional issues are raised, may be tabled. At the meeting the committee may instead vote to send the protocol to designated review for approval when minor corrections are still needed if they do not feel the issues require a return to the full committee.

Forms

All forms are available on the compliance website: *www.ohiou.edu/research/compliance.*

IACUC Full Application Form: used for new protocols, including invasive field studies.

IACUC Exempt Field Study Form: used if the investigator is doing field study research that is non-invasive, such as observation of behaviors.

IACUC Purchased Antibody Form: used if investigators use antibodies commercially manufactured especially for them.

Health and Safety Form: Investigators and all personnel, including students, who will work with animals on a project must also complete this form in addition to the application to use animals.

IACUC Application to Amend an Approved Protocol: used if an investigator needs to amend an already approved protocol.

TIP!

Uses of antibodies that are commercially available "off the shelf" do not require IACUC approval.

If you are collaborating with a researcher at another institution, and all the animal work will occur at that institution, you may apply to have IACUC approval deferred to the institution at which the animal work will occur. A copy of the protocol submitted to the other institution, and an approval form from their IACUC is required for the Ohio University IACUC to defer approval.

Assurances and Accreditations

The Office of Laboratory Animal Welfare (OLAW), within the US Department of Health and Human Services, is the agency charged with overseeing animal research. OHIO has an OLAW-approved assurance of compliance with the HHS regulations for the protection of animals used for research and teaching. The assurance number is A3610-01.

OHIO also holds a United States Department of Agriculture (USDA) license as a research facility. The license number is 31-R-082.

OHIO's animal program is accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care, International (AAALAC, Int.).

TIP!

The federal animal subjects assurance number for OHIO is A3610-01.

Laboratory Animal Resources (LAR)

Animal Care Facilities

The research compliance website, *www.ohiou.edu/research/compliance,* contains important information for investigators wishing to use the animal facilities. All vertebrate animals must be housed within the animal care facilities unless a specific exception has been granted by the IACUC. To house animals within the animal facilities, the investigator must apply to the IACUC for approval to conduct the work and also contact LAR to determine availability of space for the project. OHIO animal facilities do not contain centralized support services such as surgical assistance, but individual assistance with many procedures may be obtained by contacting LAR.

DON'T FORGET

All vertebrate animals must be housed within the animal care facilities unless a specific exception has been granted by the IACUC.

Animal Care Per Diems

Investigators are charged for the care of all animals housed at OHIO and an account number must be supplied for animals to be housed. Account number(s) to which per diems will be charged are asked for when animals are ordered. New investigators may use start up accounts if they are not transferring grants to OHIO. Animals granted exceptions by the IACUC to be housed and cared for in investigator laboratories are also charged a per diem and LAR will check on them each day to assure standardized care. Current per diem rates are available on the compliance website, ***www.ohiou.edu/research/compliance****.* These applications for interim coverage are subject to available funds and may not always be accessible.

TIP!

Investigators temporarily without funding, such as investigators between grants, may apply to the Vice President for Research for coverage of their per diems for a limited time.

Animal Purchases

All animals must be ordered through LAR. An account number(s) is asked for when orders are placed. Receipt of animals is through the LAR office, unless a specific exception has been granted.

DON'T FORGET

All animals must be ordered through LAR.

Environmental Health and Safety

A large part of university compliance deals with the safe management of labs and other research space, especially when dealing with chemicals and other potential toxic substances.

This section introduces researchers to OHIO health & safety policies and procedures, the Environmental Health & Safety Department (EHS), major components of lab safety, biosafety and radiation safety, as well as regulatory items pertaining to Ohio Public Employees Risk Reduction Act, Occupational Safety and Health Administration, Environmental Protection Agency, National Institutes of Health, Ohio Department of Health, and the Nuclear Regulatory Commission. This section is not meant to be all-inclusive, but rather a primer for creating and maintaining a safe and healthy research environment. Contact EHS for specific information and guidance.

University Environmental Health and Safety Policies

Below is a list of environmental health & safety related policies and procedures for OHIO. Please review these policies via either the hard copy or online ***(http://www.ohiou.edu/policy/index.html)*** University Policy & Procedure Manual.

- 44.104 - Hazardous Materials Management
- 44.105 - Fire Emergencies
- 44.106 - Chemical or Radioactive Spill Response
- 44.107 - Biohazards
- 44.108 - Hazardous and Radioactive Waste
- 44.109 - Safety Policy
- 44.110 - Reporting Hazardous Conditions
- 44.111 - Investigation of Non-Radiation Injury Incidents
- 44.115 - Environmental Health and Safety Code
- 44.118 - Occupational Safety and Health Implementation Policy

Environmental Health and Safety Department

EHS is responsible for coordinating most aspects of environmental management, health and safety on campus, and implementing safety regulations for the University. EHS staff members are available as technical consultants to the campus community. The department employs highly qualified, applied scientists/administrators in the areas of radiation safety, hazardous materials management, environmental management, public health sanitation, occupational health and safety, biosafety, lab safety, infectious waste, fire/life safety, and training.

There are two types of environmental health & safety programs at OHIO:

1) Department Level Programs: this includes the Chemical Hygiene Program (CHP), the Bloodborne Pathogens Program (BBP), and Biosafety Program. Although EHS staff provides oversight and technical support, all department level programs are implemented and managed by department chairs and their designees.

2) University-Wide Program: this includes the Infectious Waste, Radiation Safety, and the Hazardous Waste Programs. University-wide programs are developed, implemented and managed by EHS.

Administrative Procedures For Researchers

As the PI/PD in your laboratory or research space, it is essential that you establish a proper standard operating procedure that complies with the applicable federal, state, local, and university rules and regulations. You must also create and maintain a safe and healthy research environment.

When beginning to design your standard operating procedure for your lab, you should first write a specific Chemical Hygiene Plan (CHP). You must review this plan annually, allowing any necessary adjustments to be made as you progress in your research. In your CHP, you should identify individual PI/PD procedures and any other special situations. A Chemical Hygiene Officer (CHO) must be desingated for your home department.

Departmentally, a safety/audit committee needs to be established and be active. This means that there should be student safety policies established that mirror all employee/lab standard practices. A department needs to establish a communication system/mechanism to quickly disseminate environmental, health, and safety information. A departmental policy should be created for dealing with small quantity purchases and waste minimization. Lab maintenance and testing duties should be assigned to appropriate staff members. This includes the posting of House Bill 308 “Public Employees OSHA” poster on all department public bulletin boards, as well as the posting of all lab rules (standard operating procedures), assuring that fumehoods are available and working properly, assuring that the OHIO Hazardous Materials Policies (44.101 and 44.108) are being followed and that all appropriate chemical and safety reference materials, books, etc. are available as needed.

Should you have visitors to your lab space, there should also be a visitor policy developed which requires compliance with the lab safety requirements. Visitors, contractors and maintenance personnel must be informed of all lab hazards and requirements. Before beginning your research involving EHS monitored materials, your research project must have the appropriate institutional approvals and numbers (Radiation Safety Committee, Institutional Biosafety Committee, Institutional Review Board, Institutional Animal Care & Use Committee, etc.) before an account will be established. The EHS staff will work closely with the ORSP staff to ensure that all conditions have been met before research can begin.

Before beginning your research involving EHS monitored materials, your research project must have the appropriate institutional approvals and numbers (Radiation Safety Committee, Institutional Biosafety Committee, Institutional Review Board, Institutional Animal Care & Use Committee, etc.) before an account will be established.

Once you have begun your research, you must be certain to keep detailed records that include:

- Written CHP and Material Safety Data Sheets on file
- Training records for staff (general CHP)
- Training records for staff (lab/chemical specific)
- Annual review of CHP documented
- Incident reports and follow-up

All accident/incidents occurring in the lab (including “near misses”) must be reported to EHS on an OU Incident Report Form. State needle-stick forms are available at ***http://www.ohiou.edu/ehs/indLinks.html.*** Preventive actions are initiated.In coordination with EHS staff, a department should have a policy established and enforced for faculty lab cleanout and/or departure from the university. All of the above procedures should be communicated to the department staff before beginning a research project through an employee training program.

Chemical Hygiene Management and Lab Safety

OHIO conducts a large amount of research that requires the use of laboratories. These laboratories have many unique materials and concerns that require safe handling procedures, equipment, training, and other control measures. Special research safety equipment, including fumehoods, safety showers, eyewashes, and other controls must be maintained and tested. Laboratory personnel and departments must maintain their OSHA Chemical Hygiene Plans. OHIO's EHS Department audits these laboratories, assists with waste disposal and other issues, and offers technical assistance as needed.

The following are chemical safety requirements in all OHIO laboratories:

- Chemicals are stored by chemical classes and separated vertically and horizontally from incompatibles (not alphabetically)
- Chemical containers are dated when received and when opened. Date-sensitive materials are controlled and disposed of when needed.
- Peroxide-formers, shock and water sensitive and other special materials are stored properly
- Chemical containers are wiped and capped immediately after use to avoid spills and off-gassing
- Chemical storage cabinets or shelves are sturdy, secured to floor/wall, stable and have lips, curbs, ropes or other "knock-off" protection
- Secondary containers are used for chemicals when necessary
- Chemicals are not stored in fumehoods (use appropriate flammable cabinets, acid cabinets, or containers)
- Flammables are stored in approved flammable storage cabinets
- Flammables outside the flammable storage cabinet are not stored over daily working amounts
- A chemical inventory is available and material safety data sheets (MSDS) are available for all chemicals used in the lab
- The chemical inventory and MSDS's are maintained and a system is in place to add/delete/archive MSDS's
- MSDS is obtained and hazards evaluated before purchase
- Old chemicals are properly and legally disposed of and not allowed to accumulate
- All chemicals are properly labeled

The following are lab safety requirements of all OHIO laboratories:

- Signage on the lab door and inside lab has appropriate warnings, symbols, safety information, and names and phone numbers of PI/PD, lab director, and alternates
- Lab housekeeping is good and a system is established for set up, dismantling, and clean up
- Aisles are clear and unobstructed; avoiding slips, trips, and falls.
- Personal Protective Equipment (PPE) needs have been evaluated, documented in writing, and necessary equipment is provided and used
- Cylinder gases are properly secured, used, and transported
- Incompatible gases, flammables, oxidizers, etc. are separated
- Lab sinks are free from contamination and thoroughly rinsed with water
- Appropriate use of extension cords or temporary wiring
- Unattended reactions or operations are minimized or forbidden.
- Chemical toxicity and exposure potential is evaluated, routes of exposure are considered
- Minimize mercury use - replace mercury thermometers with other types if possible
- Egress routes from lab are established, not blocked, and known
- Respirators are not used (unless proper evaluation by EHS and enrollment in Respiratory Protection Program is completed)
- Department has appropriate research apparatus/shop design reviews and safety considerations established for the design construction of "home-made" research equip ment and apparatus
- High hazards chemicals, carcinogens, mutagens, are stored in secure, labeled area or cabinet (a designated area, per OSHA)
- Unsafe conditions are corrected immediately or referred to appropriate academic or administrative offices

Lab employees and visitors must adhere to the following:

- No eating, drinking, tobacco products, application of cosmetics, or taking medicine in the lab
- Proper lab technique is required at all times (experiential procedure established, proper chemistry techniques followed)
- Labs should not be used for office space
- Appropriate lab attire (lab coats, no shorts, no open-toed shoes, etc) required
- Refrigerators are maintained and clean
- No food, cosmetics, medicines, personal items stored in lab refrigerators
- Hand washing sink, soap, and towels are available and used
- Heat sources and flames are not used around flammables

Emergency Preparedness and Spill Response

Tornado, chemical spill, fire and flooding are believed to be the sources of the greatest risk for an immediate emergency that would be dangerous to life and health. Therefore, it is essential that laboratory personnel are trained on emergency preparedness and response. Each laboratory shall be equipped with an accessible phone including posted emergency phone numbers. Each laboratory where corrosives and other chemical eye hazards exist shall be equipped with an eye-wash and safety shower. The safety shower/eyewash is to be thoroughly tested at least monthly and documented. Safety equipment such as fire extinguishers must not be blocked or obstructed and must be readily available. Pre-arrangements should be made with emergency or medical services for any special needs (neutralizers, antidotes, special medical, etc.). Laboratory spills that are within the scope of the researcher to clean up shall be cleaned immediately. Emergency/spills larger than the investigators ability to clean should be referred to EHS or the OHIO Police Departmetn (OUPD). Spill kits should be maintained in the laboratory areas that are available to each laboratory or group of laboratories. Where mercury has the potential to be spilled, contact EHS for help in cleaning up such spills.

Each laboratory where corrosives and other chemical eye hazards exist shall be equipped with an eyewash and safety shower.

Recap of Key Emergency Laboratory Equipment and Procedures Required:

- Lab phone is available with emergency phone numbers posted
- Lab has safety shower/eyewash available
- Safety shower/eyewash is thoroughly tested at least monthly, with reminder sheet posted
- Safety equipment is available, operational (shower, eye wash, fire ext., fire aid kits, etc.)
- Safety equipment is tested, checked, refilled regularly
- Safety equipment is not blocked or obstructed
- Provisions have been made with emergency or medical services for any special needs (neutralizers, antidotes, special medical, etc)
- Spills are cleaned up immediately and emergency/spills kits are available in the lab areas
- Clean up materials and absorbents available for mercury collection and clean up
- Spill clean up kits are maintained and stocked as needed

Spill Response - Establishing the Significance

significant spill: **one that needs additional help, is life threatening, flammable, toxic or radioactive or if the chemical spilled is unfamiliar to you.**

Spills at OHIO are considered either significant or insignificant. What determines significance? If additional help is needed the spill is considered significant. The amount of the chemical or radioactive material spilled is not the major concern. The major concern is the life threatening potential of the spill. Flammability, chemical toxicity, radiation level, and concentration are very important factors in determining whether a spill is significant or insignificant. If the containers of chemicals around you are not familiar, then any spill is of concern.

In all other cases, make an initial assessment of the situation with your senses:

- Does it smell bad?
- Is it hurting the eyes, nose, or throat?
- Does the material cause choking or difficulty in breathing?
- Does the material cause nausea?
- Does the material cause dizziness?
- Is the material smoking, sizzling, or hissing?
- Is the spill in a chemistry lab (as opposed to being in a kitchen)?

If all of the above questions' answers are "no," then it is possible the spill should be considered insignificant (even though it may have chronic health or environmental significance). The last question is based on the fact that chemicals in laboratories are more likely to be concentrated or highly reactive than the commercial and consumer products commonly found in kitchens. If all of the above questions' answers are "no," then you can usually take the time to read the label or MSDS, and from that information decide whether the spill should be considered insignificant and cleaned up, or the spill should be considered significant and help should be called.

If you are familiar with the contents of containers and the environment where a spill occurs, you can choose a commensurate response based on your knowledge about the chemicals. For example, the chemical may smell bad or burn the eyes and throat, but you may know that these mild symptoms occur even at concentrations that are not harmful. In this case, you would consider the spill to be insignificant. If a chemical is regularly used, then its properties are likely to be well known. This very same chemical spill might well be a significant spill to a different person, who did not have the detailed knowledge about that chemical. For the purpose of this procedure, if it is necessary for additional help to be called, consider the spill to be significant.

Spill Response - Significant Spills

In all cases of significant spills, call 911 and the Fire Department will make an assessment based on information and other resources available, and will decide what actions to take. All instructions will come from the person in charge at the scene. This will be the Fire Chief unless otherwise delegated. If the Fire Chief determines the spill will affect more than one building, then a university-wide alert shall be sounded. If it is believed that an alarm response is not warranted, and it is decided not to pull the fire alarm or call 911, seek the opinion of the immediate supervisor or contact EHS: phone 593-1666 and ask for a person in charge. If individuals are familiar with the spilled material and are comfortable with cleaning the material up, it should be cleaned up cautiously. If the material is well isolated, but it is known the room is not safe to be occupied, EHS will assist in contacting a chemical or radioactive spill cleanup team. In this case, clearly label all entrances to the space with signs "Do Not Enter, Chemical (or Radioactive) Spill."

TIP!

The person in charge at the scene of a significant spill resulting in a 911 call will be the Fire Chief unless otherwise delegated.

If the spill is considered significant, then the appropriate response will depend on whether the location is indoors or outside.

- The fire alarm shall be activated and the building must be evacuated.
- When leaving, close the door and notify as many people as possible that there is a chemical spill and where it is. (A warning, "Chemical (or Radioactive) Spill," should be communicated to all.)
- Ensure the alarm has been reported by calling 911.
- Wait outside for the Fire Department to arrive and report to the Fire Chief or designated person in charge.
- The acronym C.A.R.E. is an easy way to remember what to do. The procedure may not be in the same order. Close the door, activate the Alarm, Report the incident, and Evacuate the building.

DON'T FORGET

The acronym C.A.R.E. is an easy way to remember what to do. The procedure may not be in the same order. Close the door, Activate the Alarm, Report the incident, and Evacuate the building.

Spill Response - Outside of a Building

- Stay clear of danger.
- Call 911 and report the spill.
- Do everything possible to keep others away from the spill without risking personal safety.
- Wait for the Fire Department to arrive and report to the Fire Chief or designated person in charge.

Recap of Key Spill Response Questions

- Is the material flammable?
- Could there be a fire or explosion?
- Might the space ventilation system carry vapors, fumes, or dust to another space?
- Can the crack around the door be sealed so the vapors will not flow into the hallway?
- Is there a path for a liquid to run down to the next level? (This can be around pipes that go through floors under sinks, pipes that may be hidden by cabinets. It is recommended the room below be secured just in case.)

When the spill situation requires judgment calls. always err on the side of safety. Do not take chances. The Fire Chief, Ohio University Police Department, and EHS have the emergency pager number to contact a contractor for emergency chemical or radioactive spill cleanup.

Fumehoods, Biosafety Cabinets and HVAC

Many labs utilize fumehoods, biosafety cabinets, or other local exhaust ventilation to maintain a safe & healthy atmosphere within the lab space and to protect the research from cross contamination. OHIO has special hoods or ventilation devices available such as perchloric hoods and Atomic Absorber vents. All lab fumehoods and biosafety cabinets must be registered with EHS. All fumehood filters in place should be maintained and changed regularly. Any duct-less hoods must be approved by EHS prior to purchase and use, and filters should be maintained and changed regularly. Lab room differential pressure (e.g. negative pressure) is acceptable. Lab air should be relatively odor-free.

Hazardous and Infectious Waste

The primary tools used to determine if a material is hazardous and how it will be handled are the Material Safety Data Sheet, the container label, and shipping papers.

The secondary tools to determine if a material is hazardous are the specific listings and definitions of materials addressed in various regulations. These lists and definitions are contained in the U.S. Code of Federal Regulations, Ohio Revised Code, Ohio Administrative Code, all of which may be found at Alden Library. The third tool is personal knowledge; an individual may have created the material, or know very specific information about the materials properties.

***"Hazardous material"* is any material or substance which, if improperly handled, can be damaging to the health and well-being of humans and their environment.**

***Material Safety Data Sheet (MSDS)* is a regulatory document that is required to be provided by the manufacturer to the user; the sheet contains pertinent safety information.**

TIP!

If hazardous material status cannot be determined, call Environmental Health and Safety and request a review by the Hazardous Materials Manager.

The safe storage, treatment, and disposal of infectious waste at OHIO is regulated by the State of Ohio Infectious Waste Regulations, which are enforced by the Ohio EPA and the Athens City-County Health Department, who inspects the campus program quarterly. OHIO maintains an Infectious Waste Management Program. For detailed regulatory definition, see the Biosafety Manual, which is linked from ***http://www.ohiou.edu/ehs/docs/Biosaf_Manual_R.doc*** and state regulations, or contact EHS.

***"Biohazard Waste"* is any substance that is no longer of use and contains or could potentially contain biohazardous agents.**

***"Infectious Waste"* is made up of waste materials to be discarded that may contain infectious agents, cultures, blood products, needles, and other materials that may cause disease in humans.**

***"Radioactive Waste"* is any substance that is no longer of use and is known or suspected of being contaminated with radioactive material or any waste that releases radiation greater than background level.**

Waste streams should be categorized, labeled, covered, and disposal methods established for:

- normal trash
- animal carcasses
- hazardous/chemical waste
- radiation waste
- infectious waste
- non-contaminated sharps and glass

The department shall maintain a registry of acutely hazardous chemicals (AHC) in each laboratory with information regarding each chemical's hazards, physical and chemical properties, antidotes, precautions, and clean-up procedure. The registry and chemicals involved shall be discussed with personnel who will work in that laboratory prior to allowing them access to the laboratory. A copy of the registry list shall be sent to EHS and updates telephoned in when an AHC is added or discontinued.

A list of waste that will be generated, including the route of disposal for each waste should be maintained. Students and other staff generating waste should be taught to identify the type of waste stream and instructed on the appropriate route of disposal.

When disposing of waste:

- Waste chemicals in the lab are labeled with EHS waste labels until pick-up.
- Waste chemicals are stored in secondary containment until pickup in case of leaks or spillage.
- Ensure all wastes are identified, packaged, and removed in accordance with the appropriate manual and guide, on a continuous basis.
- Inspect areas that have generated waste, to insure the area is clear of all waste prior to termination of responsibility in that area.
- Limit ordering of waste source materials to the amounts needed. The disposal cost of waste typically exceeds purchase price of the material.
- Be cognizant that steps can be taken to detoxify or neutralize waste and include those steps in the generation procedures as practical.
- Practice waste reduction.

Limit ordering of waste source materials to the amounts needed. The disposal cost of waste typically exceeds purchase price of the material.

Biological Safety

Biosafety involves the safe use of biological materials in research, such as infectious or disease containing organisms, recombinant DNA technologies, bloodborne pathogens, human tissues, vectors of disease, and zoonotic agents, among others. The Biosafety Officer at EHS works with the Institutional Biosafety Committee (IBC), a group of faculty research experts and community representatives to help insure safe research protocols, labs, and equipment. Guidelines issued by the Centers of Disease Control and Prevention and the National Institutes of Health are adhered to. OHIO maintains a Biosafety Program and Manual for researchers.

All persons intending to use the listed materials for research, teaching or related purposes on or off campus, must receive the approval of the IBC prior to beginning the work. A risk assessment will be conducted by the principal investigator, and information submitted to the IBC, in the form prescribed by the committee; dealing with the laboratory facilities, clinical or field protocols and procedures, containment methods, emergency procedures, waste disposal, occupational health and safety, regulatory compliance and other information as required. Approval of the IBC will be in writing for all experiments.

Recap of Key Biosafety Points:

- Projects must be reviewed and have received an IBC approval number
- Biological labs meet OHIO Biosafety Program and CDC/NIH guidelines
- Labs working with blood or other potentially infectious materials have a written and implemented OSHA Blood Borne Pathogens (BBP) Plan
- No organisms or toxins are permitted for use at OHIO that are regulated by the federal “Select Agent Transfer or Possession Laws” nor are BSL3 or BSL4 organisms. This is because OHIO lacks the proper facilities at this time.
- Biosafety cabinets tested and recertified annually, when new, and when moved.

Radiation Safety

Radiation Safety is responsible for supervising the daily activities of the Radiation Safety Office. This entails monitoring the dosimetry and bioassay programs, overseeing all facilities using radioactive material as to safety and compliance, receiving, processing, delivering and keeping inventory of all radioactive materials, training, instrument calibrations, sealed sources, and radiation-generating equipment. Also, radiation safety interacts with the various Federal and State agencies and OHIO’s Radiation Safety Committee, which establishes policy and assures regulatory enforcement within the university community. Radioactive material users must be properly authorized by the Radiation Safety Committee (RSC), trained, and in compliance with NRC/ODH/RSC guidelines. All users of radioactive material must apply to the RSC for authorization to obtain, use, store and dispose of radioactivity, regardless of the form. They must also receive orientation training from the Radiation Safety Office prior to authorization being granted. Radioactive materials can be used only in a particular RSC approved lab room.

TIP!

All users of radioactive material must apply to the radiation safety committee for authorization to obtain, use, store and dispose of radioactivity, regardless of the form. They must also receive orientation training from the Radiation Safety Office prior to authorization being granted.

All areas involving the use of ionizing or non-ionizing radiation (lasers, UV, IR, EMF, sealed/unsealed sources, etc.) must be inspected by the Radiation Safety Office as to applicability, safety features and compliance with University programs in place. In accordance with the approval above, physical non-ionizing radiation sources (lasers, UV, etc.) are being safely used, labeled, categorized and maintained. Specialized eye protection or other safety devices are to be used properly.

Regulations stipulate that anyone visiting a restricted area where radioactive material is authorized to be used, stored or disposed, must receive a “hazardous” awareness training by someone from that lab. The occasional visitor who needs to come in radiation labs must receive orientation training from the authorized user in that restricted area.

Incident Investigation

EHS is responsible for coordinating the investigation of injury incidents. Every minor or non-disabling injury will be investigated with the same vigor and thoroughness as serious injuries. Minor or non-disabling injuries occur in relatively substantial numbers. Proper and complete investigation of these injuries can be an effective tool to prevent both similar and more serious injuries.

The supervisor, under whose direction the employee is working, is responsible for conducting a complete and thorough investigation. He or she should record the findings in writing on the University Incident Investigation Form ***(http://www.ohiou.edu/ehs/indLinks.html)*** form, in triplicate: sending the original to the Workers’ Compensation Administration office, the second copy to the Departmental Head, and the third copy to the supervisor. The Workers’ Compensation Administration office will send a copy to EHS.

Incident Investigation Forms must be completed in triplicate!

All Injury Investigation Reports will be reviewed by the Safety Officer in EHS to ensure that all pertinent information has been obtained and that remedial action will be taken. In the case of serious or unusual injuries, the Safety Officer will thoroughly investigate the incident. In some cases it may be desirable to secure photographs, drawings, or other exhibits as attachments to the fact finding report, so that the facts involved in the incident will be clear. Reports should include detailed statements from all witnesses to the incident, as well as others who can provide information about the incident, if warranted.

Immediately after an injury or incident, the first step is to ensure that the injured person receives proper medical care. Call 911 for all emergency medical services. You should take the employee to the Occupational Health Clinic (or another medical facility) for medical evaluation and management in less severe cases. Then notify the Ohio University Police Department as soon as possible. After the injured person has been properly cared for, the injury investigation procedure should be started promptly by the supervisor and submitted as outlined above. To the fullest extent possible without compromising safety, all the conditions that existed at the time of the incident should remain until the investigation is completed.

TIP!

**Call 911 for all emergency medical services needed as a result of an incident.
All non-emergency injury victims should report to the
Occupational Health Clinic.**

Follow-Up Action:

- It is important to include in the Injury Report the specific actions that will be taken and the deadline for their completion. The supervisor should follow-up to assure that the specified actions have been taken.
- After the investigation is completed and remedial actions taken, the facts involved, findings developed, and remedial steps taken, should be brought to the attention of all employees in the incident area, and to those working on similar operations. The purpose of this communication is threefold:
    - o To provide additional safety training based on the facts involved in the incident;
    - o To let employees know about the actions taken to protect their safety; and
    - o To prevent future incidents.
- It is desirable to get employee suggestions because of their intimate contact with actual working conditions. Also, participation by employees encourages their cooperation in avoiding unsafe acts or practices and in preventing future injuries.

Training

EHS maintains an extensive training catalog with courses offered every quarter. EHS keeps a record of all employees attending EHS-sponsored training. Some courses are open enrollment; however, many are required only of certain employees to meet regulatory requirements and some have prerequisites. There are some training courses that are required annually. Supervisors are responsible to keep track of the training required by law for their employees and to keep appropriate records. Supervisors are responsible to know when their employees are required to attend training and to make arrangements for them to register on time and get to it. EHS publishes a training catalog and course information on the EHS website at: ***http://www.ohiou.edu/ehs/training.htm.***

Laboratory staff must have the following training:

- **All employees that use chemicals in the lab (including grad and teaching assistants) must attend chemical hygiene (lab safety) training (general CHP training and lab-specific training).**
- Lab staff must understand fumehood flow alarms, audible alarms, magnehelic gauges and what to do when indicators go off. Alarms are not disabled.
- Staff should be trained on the use of fire extinguishes, fire prevention, and egress.
- Appropriate members of your department should receive EHS Lab Safety, OSHA, and Radiation Safety Newsletters.
- Safety orientations for all graduate students, teaching assistants, research assistants, technicians, post-doc's and visiting professors must be completed.
- All employees using radioactive isotopes or equipment in research must receive radiation safety training annually.
- All research employees should be trained on spill clean up & emergency response.

All training is documented and annual refresher courses for specific programs are attended.