Temple University
Environmental Health and Radiation Safety

REFERENCE GUIDE FOR PRINCIPAL INVESTIGATORS

Published by

Temple University

Environmental Health & Radiation Safety

July 2020

Table of Contents

I. Introduction

EHRS Welcomes You to Temple University

This guide is an introduction to the Environmental Health and Radiation Safety (EHRS) Department for principal investigators (PIs) who are new to Temple University (TU) and is a reference tool for any principal investigator. It outlines your health and safety responsibilities as a PI and provides links to related resources.

As a PI, you are responsible for the workplace safety of everyone who works in your laboratory and for the requirements outlined in this guide. You may delegate safety–related tasks to others, but you retain ultimate responsibility.

Contact Information

Web pages and contact information for specific issues are listed throughout this guide. See the EHRS website for a list of contact information by topic.

Environmental Health & Radiation Safety (EHRS)
Pharmacy-Allied Health Building
3307 N. Broad Street, Room B-49
Philadelphia, PA 19140
Phone: (215) 707-2520
Email: ehrs@temple.edu
Web: www.temple.edu/ehrs

EHRS Resources

EHRS offers training, consultation, and information regarding laboratory safety. The EHRS website has a variety of safety information and resources. EHRS provides resources and guidance for researchers to stay safe and compliant with local, state and federal regulations and policies at all TU campuses and facilities. However, specific policies and procedures may vary by location.

II. EHRS Registration

New PIs and their associated work space and personnel must be registered using the Laboratory Registration Form with EHRS. This information is required to facilitate regulatory compliance, improve emergency response time, assist with future reporting requirements and notifications and assures the safety of students, staff, visitors and emergency responders.

In addition, this information is entered into the EHRS database which enables us to assist you in the timely submission of any required applications and authorization.

Completed laboratory registration forms should be submitted to EHRS via email (ehrs@temple.edu)

An EHRS representative will contact you when the form is received and arrange for a time to meet with you personally after your arrival at TU. This appointment is informal and structured as a time for you to ask question, go over EHRS requirements, resources and services we provide. You can also contact EHRS at (215) 707-2520 to request an appointment.

III. Required Authorizations

PIs must obtain authorizations before beginning research involving biohazardous materials, radioactive materials, controlled substances, laser, infectious agents, recombinant and synthetic nucleic acids, biological toxins (including CDC-defined Select Biological Agents), OSHA-defined hazardous drugs, DURC agents, human subjects, animals or other living organisms.

Refer to the applicable sections below for information regarding the authorization requirements and the procedures for the application procedures.

Allow for processing time. Apply well in advance of establishing your lab. Approvals may take several months to process and approve.

IV. Research Grant Approvals

Many research grants require institutional approval or periodic renewals prior to the submission of a grant proposal or annual renewal for the dispersal of the grant's monetary awards. This dispersal of grant funds may require that Principal Investigators file an Assurance on Hazardous Procedures (AHP) form with Temple University's Office of Sponsored Projects and receive approval from that office. AHPs are referred to EHRS for safety compliance review to ensure that the facilities, processes, and materials are sufficient to provide a safe environment for laboratory workers, staff, students, and visitors.

See the Office for Vice President for Research (OVPR) for more information on grant review and administration.

V. Training

As the PI, you are responsible for ensuring that all of your staff are trained on the hazards they will encounter while working for you. EHRS provides classroom and online courses that address various types of hazards and regulatory requirements.

EHRS Training Webpage

Visit the EHRS Training webpage to see a list of current courses, register for classroom courses and complete online courses.

Use the EHRS Training Course Matrix to find courses that address job-specific hazards.

Laboratory-Specific Training

In addition to general courses taught by EHRS, all laboratory staff are required to have laboratory-specific training on the hazards they may encounter while working for you. This training is usually conducted by the PI, Lab Manager, or a qualified designee.
Laboratory specific training includes standard operating procedures for all hazardous materials and hazardous activities in the laboratory.

VI. Biological Safety

At Temple University multiple administrative committees are involved in the oversight of the use of biological materials, agents that may present a biological hazard to staff or students. The University requires that Principal Investigators submit research applications to the appropriate committee(s) and receive formal, written approval from those committees prior to the initiation of work involving the use of biological materials, including human subjects. These committees include the Institutional Biosafety Committee (IBC), the Institutional Animal Care and Use Committee (IACUC), and the Institutional Review Board (IRB).

EHRS assists these committees by reviewing the submissions with respect to biological safety and compliance to federal, state, local, and University regulations, guidelines and policy, regarding the possession and experimental use of biological materials. EHRS also reviews biological-related Material Transfer Agreements (MTA) submitted to the Office of Technology Commercialization and Business Development (OTCMBD) for the same concerns.

EHRS assists researchers by providing consultation regarding facility design plans, laboratory containment of biologicals, and the handling of biohazardous waste.

Through periodic biological safety surveys, EHRS assists researchers in achieving and maintaining compliance with federal, state, local and University regulations, guidelines and policies.

For more information, see the Biological Safety section of the EHRS website.

Biohazardous Agents and Procedures

Recombinant and synthetic nucleic acids, as defined by the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*), possession and experimental use must be registered with and approved by the Institutional Biosafety Committee (IBC). This registration and approval is in accordance with Temple University policy and is mandated by the NIH for all researchers at any institution receiving any funding from the NIH. Administration of these agents to animals or humans additionally requires IACUC and IRB approval, respectively.

Genetically modified organisms may pose a biological risk to humans and the environment. Containment of these is a primary concern, in addition to the possession and use of these organisms. IBC and IACUC review and approval are required.

Gene editing technology procedures such as the use of Clustered, Regularly Interspaced, Short Palindromic Repeats (CRISPR), Transcription Activator-Like Effector Nucleases (TALENS), and Zinc Finger Nucleases (ZFNs) must be approved by the IBC. Additional approvals may be required if this procedure is applied to animals (IACUC) or in a clinical setting (IRB).

Pathogenic agents are disease causing organisms from the following groups: viruses, bacteria, fungi, and parasites, which include protozoa, and helminths (worms). Possession and use of these agents must be approved by the IBC and, if applied to animals, the IACUC.

Bloodborne pathogens (BBP) and Other Potentially Infectious Materials (OPIM) include human and non-human primate-derived samples including blood, cells (primary or cultured), tissues and body fluids, unless they have been tested and certified to be free of pathogens. IBC registration and approval are required for the possession and experimental use of these agents. IACUC approval may be required if these agents are administered to animals. IRB approval may be required for the collection and/or use of human-derived samples.
Roles and responsibilities for use and/or storage of BBP and OPIM:

- The Principal Investigator must inform all staff, within ten days of assignment of tasks in which there is a reasonable potential for exposure to BBP or OPIM, that Temple University provides, free of charge, the Hepatitis B vaccine.

- Employee immunization and titer records are confidential and maintained by the Department of Human Resources.

- Employees may decline Hepatitis B vaccination. An immunization declination form must be completed and personally filed, to maintain confidentiality, with Human Resources.

- The Principal Investigator is required by OSHA (29CFR 1910.1030) to develop a written, site-specific BBP Exposure Control Plan (ECP). This plan must be reviewed at least annually or with personnel changes or changes in an individual's assigned tasks.

- The Principal Investigator must train staff on the ECP prior to their commencement of work with the BBP/OPIM and then annually, thereafter, to ensure adherence to the ECP.

- The Principal Investigator must complete the initial EHRS Bloodborne Pathogens training and annual refresher training.

- The Principal Investigator must direct and ensure all staff complete the initial EHRS Bloodborne Pathogens training and annual refresher training.

Biological toxins (including Select Biological Agents [SBA]) are biological agents and toxins that are considered to present a potentially severe threat to health and safety to humans, animals, plants and animal and plant products. Possession and use of SBA is regulated through the Federal Select Agents Program (FSAP), which is administered jointly through the Centers for Disease Control and Prevention (CDC) and the Animal and Plant Health Inspection Service (APHIS). Possession and use of all biological toxins must be registered with and approved by the IBC.

Dual Use Research of Concern (DURC) is life sciences research that may provide knowledge, information, products or technologies that, in misapplied could present a significant threat to public health and safety, agricultural crops and other plants, animals, the environment or national security. The United States Government Policy for Institutional Oversight of Life Sciences Dual use Research of Concern (September 2014) articulates the practices and procedures of DURC potential.

Principal Investigators must notify the IBC of intent to possess, produce or use these agents. Institutional oversight (IBC) is required by the federal government.

Biological Safety Training

Biological safety training is required for all researchers, including PIs, collaborators, visiting scientists, post-doctoral fellows, graduate and undergraduate students, technical staff and volunteers working with potentially biologically hazardous agents. These agents include, but are not limited to, recombinant or synthetic nucleic acids, bloodborne pathogens, select biological agents (SBA), dual use research of concern (DRUC) agents, biohazardous waste and NIOSH-defined hazardous drugs. Safety trainings are provided and maintained by EHRS.

Because the above training does not cover all possible biological safety concerns encountered in each individual lab, Principal Investigators or their designee(s), who are knowledgeable and competent in the experimental protocols, are required to provide laboratory-specific training in the procedures used in that laboratory to all relevant staff.

Biological Safety Cabinets

A Biological safety cabinet (BSC) is a primary engineering control used to protect against personal exposure to and environmental release of the biohazardous or infectious agents.

BSC function must be certified on an annual basis by a licensed outside vendor. If the annual certification date is exceeded, the BSC must not be used until it is recertified. Recertification must also be performed when a BSC is relocated.

Biological safety cabinets should not be confused with chemical fume hoods in their function. BSCs use HEPA filtration to purify exhaust air of potentially biohazardous particulates prior to exhaust into the room. Unless specifically equipped/ducted, they are not appropriate for use with chemical vapors.

Chemical fume hoods are not equipped to remove potentially biohazardous particulates from exhaust air and should not be used for procedures involving biologically hazardous materials.

VII. Chemical Safety

If you use hazardous chemicals in your laboratory, you must have the following documents and practices to meet the minimum regulatory requirements.

Chemical Hygiene Plan

If you use hazardous chemicals in your laboratory, federal law requires that you have a Chemical Hygiene Plan that documents safe use and management of chemicals in your

laboratory. The TU Chemical Hygiene Manual fulfills most of these requirements. However, you must assess your actual procedures for the hazards they pose and add your laboratory-specific details to the manual, including standard operating procedures (SOPs).

See the Chemical Safety Standard Operating Procedure webpage for more information and sample SOP.

Chemical Inventory (CEMS)

Temple University has Chemical Environmental Management System (CEMS), an online chemical inventory system, for you to record the identity, location, and amount of chemicals in your laboratory. It is also a central library for Safety Data Sheets (SDS).

CEMS inventories must be evaluated annually and updated after major changes in inventory. Contact information must also be current in case of emergency. If you are planning to use hazardous chemicals, you must contact EHRS to establish a CEMS account. At least one person from each lab will need to attend a CEMS training session; it does not have to be the Principal Investigator, as long as the lab sends a representative.

Hazard Signage

Hazard warning signs identifying health and safety hazards beyond the general lab hazard warning signs posted by EHRS may be required based on the type of hazard present. Examples may include lasers, magnetic field, and high voltage.

Staff Access to Safety Data Sheets (SDS)

Your staff have the right to access hazard information, usually in the form of SDS, for the chemicals they use. Chemical inventories can be printed to view hazard information. Chemicals in inventory are also directly linked to the online SDS. Anyone can access SDS through CEMS regardless if they have access to a specific lab's chemical inventory.

Access to Safety Equipment

Make sure you and your staff know where all applicable safety equipment (eyewash, shower, spill kit, etc.) is located and how to use it in an emergency.

Personal Protective Equipment (PPE)

PIs, laboratory managers and supervisors are responsible for assessing all worksites for hazards and identifying the PPE needs for all employees, students and visitors who may be potentially exposed to the hazards.

Eliminate, substitute, or design out exposure to hazards or hazardous operations, if possible. If not possible or feasible, the degree of hazard and engineering or administrative controls in place will determine what PPE is needed.

Laboratories should refer to the Laboratory Guidance on Chemical Hazard Controls for assistance in determining appropriate PPE for laboratory staff.

Standard Operating Procedures (SOPs)

If you operate a laboratory where chemicals are used or stored, you must have standard operating procedures (SOPs) that describe the safety measures you require when using chemicals. Please refer to the TU Chemical Hygiene Manual for more information on SOPs.

EHRS provides online resources such as chemical guides, chemical SOP library and information on SOP development for your reference.

Chemical Waste Management

Refer to the Chemical Waste Management Manual to understand your responsibilities for managing chemical waste, including identifying chemical waste, waste accumulation rules and labeling waste containers.

EHRS provides chemical waste disposal for known chemicals. Additional information can be found in the Waste Management section of the EHRS website.

VIII. Controlled Substances Used in Research

All research activities involving the use of controlled substances must be performed in compliance with all applicable laws and regulations as well as with University policies and procedures.

Controlled substances must be used under the direct auspices of a person licensed by the Drug Enforcement Agency (DEA). PIs hold individual licenses for the use of controlled substances in research. An active DEA registration for research is required prior to conducting

research with a DEA controlled substance at Temple University. Additional information on Controlled Substance Used in Research can be found on the EHRS website.

IX. Radiation Safety

Temple University management is responsible for ensuring compliance with Temple's Pennsylvania Department of Environmental Protection (PA DEP) Radioactive Materials License, Medical Accelerator License and radiation producing machine registrations. This responsibility is delegated to and enforced through the Radiation Safety Committee (RSC) and enforced by EHRS.

Radioactive Material Use Authorization

A PI must be authorized by the RSC to use or possess any radioactive material (RAM) prior to acquisition. RAM includes any material, equipment or device which contains a radioactive isotope in either a sealed or unsealed form. A PI shall request such authorization by submitting a completed New User Authorization Form to EHRS.

Radiation Safety Training

An initial, in-person radiation safety training is required for all personnel using radioactive materials at Temple University. Additionally, PIs must ensure that all personnel under their supervision receive general radiation safety training and specific hands-on, job specific training with materials, equipment or devices.

If you worked with radioactive materials at another institution and received training before, you still must attend a three-hour training session relating to TU license conditions and procedures.

Radioactive Material Management

Institutional policies and procedures for the safe handling, storage and disposal of radioactive materials and sealed sources are located on the Radiation Safety section of the EHRS website.

Radiation Producing Devices

All Radiation Producing Devices (RPDs) are regulated by the Pennsylvania Department of Environmental Protection (PA DEP) and must be registered with the Commonwealth through EHRS prior to use of the devices.

If you possess a radiation producing device, such as an X-ray fluorescence (XRF), X-ray diffraction (XRD), dental radiography, veterinary radiography, accelerator, neutron generator, irradiator, electron microscope, medial fluoroscopy, radiography and other types of radiation producing devices, please contact EHRS.

Non-Ionizing Radiation

EHRS has oversight responsibility for the use of laser and other types of non-ionizing radiation on campus to ensure these hazards are adequately controlled. The services provided by EHRS include review of facility design plans, hazard assessment, consultation on control measures and training.

If your research involves a laser, the PI has the following responsibilities:

- Registration of all Class 3B and Class 4 lasers with EHRS and updating the registration as needed, whether procured, loaned, fabricated, removed or disposed of at TU.

- Ensure that all personnel/users receive both the EHSR Laser Safety training and specific laser system training prior to initial work with laser.

- Enforcement of all laser safety requirements described in the Laser Safety Manual, with particular emphasis on facility design, laser protective eyewear, and laser safety procedures, specifically for beam alignment.

The Laser Safety Manual is available on the EHRS website.

If your research involves magnetic field, ultraviolet, radiofrequency and/or microwaves, the PI has the following responsibilities:

- Notify EHRS of the potential non-ionizing radiation hazards in your laboratory. Non-ionizing radiation sources examples:

    - Nuclear magnetic resonance (NMR) spectrometers, Magnetic Resonance Imaging (MRI);
    - UV transilluminator, crosslinker, UV germicidal lamps in biosafety cabinets, dental curing lights,
    - RF generating devices such as radio transmitters, wireless system transmitting signal at RF and MW frequencies, etc.

- Ensure that all personnel are trained and that they comply with all safety requirements.

- Provide engineering and administrative controls that will protect personnel from overexposure. This includes providing appropriate person protective equipment (PPE) to employees, visitors and subcontractors.

- Ensure that all maintenance and repair work is performed only by qualified, trained individual in a safe manner.

X. Purchasing Authorizations, Restrictions, and Notifications

Certain materials, equipment and services require university notification and approval prior to purchasing. Examples include (but are not limited to):

- Radioactive materials
- Select Agents
- Controlled Substances
- Tax Free Ethyl Alcohol (190 & 200 Proof)

Contact EHRS at 215-707-2520 if you have any questions or require assistance.

XI. Shipping Hazardous Materials

Hazardous materials include hazardous chemicals, infectious substances, radioactive materials, compressed gases, dry ice, liquid nitrogen, lithium batteries, aerosol cans, and pressurized items. Training and certification are required to ship hazardous materials via land, air or sea. There are prescriptive requirements for packaging and labeling of hazardous materials and for the associated documentation used in the event of an emergency. Training, certification, advice and packing material assistance are available through EHRS.

Radioactive materials and Select Biological Agents are shipped and received by EHRS only.

Contact EHRS at 215-707-2520 for more information.

Shipment may also be subject to Import/Export requirements. Information on these requirements and contact information can be found with the assistance of EHRS.

EHRS must also notify the U.S. Department of Homeland Security before you ship certain listed substances.

XII. Moving Into or Out of a Laboratory

Notify EHRS via the Laboratory registration form if you are moving into a new laboratory. See section II EHRS Registration above in this guide for information.

EHRS must also be notified in the event you are vacating a laboratory. Contact EHRS as early as possible since some items may take several weeks to complete in advance of your move. A Laboratory Clearance Form must be filled out, signed and approved by EHRS and posted on the door before you leave. See the Lab Safety section of the EHRS website for additional information.

XIII. Role of Environmental Health & Radiation Safety Department

EHRS communicates health and safety regulations to TU employees and provides many services related to health and safety.

Education and Outreach

EHRS provides classroom and online courses available at the EHRS training web page. EHRS publishes manuals, guides and fact sheets on various health and safety topics. See the EHRS website for a variety of information and resources.

Audits and Surveys

EHRS conduct various types (biological, chemicals, radiation, etc.) of routine audits in all research, teaching, and clinical laboratories with the intent to reduce risk, determine compliance with federal, state, and local regulations and promote a culture of safety. These audits provide guidance on training, personal protective equipment, hazardous materials management, waste handling, signage, housekeeping and other relevant topics.

Consultation

EHRS provides 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, biological safety, chemical safety, radiation safety, new laboratory set up, assistance with biosafety protocols and procures and waste management. Contact EHRS at (215) 707-2520 to schedule a consultation appointment.

Liaison with Regulatory Agencies

EHRS is the TU liaison with governmental agencies regulating environmental health and radiation safety issues. If a regulatory agency inspector arrives to initiate an inspection, contact EHRS at (215) 707-2520 to ensure proper notification and to assist with the inspection.