



University of Rochester Laboratory Safety Information

Welcome to the University of Rochester! Environmental Health and Safety (EH&S) is excited to partner with you to help ensure that your laboratory is a safe working environment and compliant with university, state, and federal regulations.

To get started, please visit the EH&S Laboratory Safety Unit's New Principal Investigator Webpage: <https://www.safety.rochester.edu/labsafety/NewPIinformation.html>. Here you will find the information needed to set up your lab safely and commission your new space. There are several required documents regarding door and equipment signage, safety equipment, and waste. The goal is to get your lab up and running as quickly as possible. To guide you along your way, we have created the [New PI Checklist](#).

Highlights:

- All members working in the lab (investigators, lab staff, and students) **MUST** complete Laboratory Safety Training **PRIOR** to beginning research. Click [here](#) to access information and directions for completing required Laboratory Safety Training.
- Register your Lab with Chematix: [New Laboratory Registration Form](#). Chematix is the University's web-based platform that handles chemical inventories, EH&S laboratory inspections, and chemical hazardous waste disposal.
- Our departmentally assigned [EHS Lab Safety Specialist](#) is available to answer questions about the potential risks presented by your research and provide necessary compliance information.

For Investigators whose research will require Institutional Biosafety Committee (IBC) approval (BSL2, NIH Guidelines for Recombinant or Synthetic Nucleic Acid Molecules), approval must be secured **PRIOR** to beginning research. See the IBC website for a [one-page summary](#) of experiments and the approval process.

For researchers who will conduct animal research, all protocols must be submitted to the University Committee on Animal Resources (UCAR). See the [UCAR website](#) for their policies and regulations.

For researchers using radiological materials, please contact the EH&S Radiation Safety Unit at (585) 275-3781 for more information.

Once you are ready to begin work, contact your departmentally assigned [EHS Lab Safety Specialist](#) to complete your initial Laboratory Safety Inspection. They will arrange a time with you to answer any remaining safety-related questions and walk through your lab space.

We look forward to working with you to provide a safe research environment.

Thank you,

Carolyn M. Place, CIH, CSP
Laboratory Safety Manager



Sonia Rosenberger, DVM, MSOH, CBSP
Institutional Biosafety Officer

Donna Douglass
Administrative Assistant
IBC Program Coordinator



INTRAMURAL CORRESPONDENCE

TO: Principle Investigators and Department Administrators

FROM: Martin Pavelka, IBC Chair 
Sonia Rosenberger, Biosafety Officer 

DATE: January 22, 2015

SUBJECT: "New Hire" Practices in Research Laboratories

The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acids state that "(a)s a condition for NIH funding of recombinant or synthetic nucleic acid molecule research, institutions shall ensure that such research conducted at or sponsored by the institution, *irrespective of the source of funding*, shall comply with the NIH Guidelines.

Noncompliance may result in: (i) suspension, limitation, or termination of NIH funds for recombinant or synthetic nucleic acid molecule research..., or (ii) a requirement for prior NIH approval of any or all recombinant or synthetic nucleic acid molecule projects..."

In addition, all violations of the NIH Guidelines must be reported to NIH even if the research is not NIH funded. The University is also required to provide the accompanying incident report to the public, if requested.

The mission of the Institutional Biosafety Committee (IBC) is to ensure that, regardless of funding source, all recombinant or synthetic nucleic acid research activities at the University of Rochester comply with the NIH Guidelines. Furthermore, the IBC ensures that all research protocols at the University that use or produce biohazardous organisms or materials requiring Biological Safety Level 2 or higher containment, including but not limited to recombinant or synthetic nucleic acids, are reviewed and found to protect personnel, public safety, and the environment.

It is the responsibility of the department where the new researchers are engaged in their research to familiarize new researchers with the appropriate documents needed to meet the safety standards set forth by the U of R, the IBC, and the NIH.

To assist with this process and reach new research investigators arriving at the University of Rochester, the IBC has composed an informational packet (attached) to facilitate registration requirements prior to starting research experiments in the lab, regardless of funding source.

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Please see the website for the Institutional Biosafety Committee. This has important information, links, and requirements designed to assist a new researcher.

<http://www.safety.rochester.edu/homepages/ibchome.html>

Thank you for your consideration in this matter and please feel free to contact us at any time!

“It is the responsibility of the Principal Investigator to comply and adhere to the NIH guidelines, for the NIH Office of Biotechnology Activities (OBA) promotes science, safety, and ethics in biotechnology through the advancement of knowledge, enhancement of public understanding, and development of sound public policies. A core responsibility of OBA is to foster awareness of, and adherence to, the standards and practices set forth in the NIH Guidelines

http://oba.od.nih.gov/rdna/nih_guidelines_oba.htm

An introduction to
UR's INSTITUTIONAL BIOSAFETY COMMITTEE (IBC)

The NIH Guidelines apply to all University PIs.

- To ensure the safe handling of recombinant materials, the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules ([NIH Guidelines](#)) require:
 - An [Institutional Biosafety Committee](#) composed of faculty, staff, and community members,
 - IBC approval of many Biosafety Level (BSL) 1 and BSL2 experiments before starting work,
 - Self-reporting violations, and making reports and meeting minutes available to the public.
- The NIH Guidelines apply to all University PIs, even if they don't receive NIH funding.

IBC approval is required before performing work that includes:

- Experiments covered by the [NIH Guidelines](#), *regardless of funding source*
 - Recombinant infectious agents if the wild-type or modified version may cause disease in people (healthy or immune suppressed), animals or plants
 - Viral vectors (including commercial)
 - Plasmids used to express or silence genes in *E. coli*, cells, animals, etc.
 - Recombinant cells administered to animals
 - Transgenic animals (new rodent strains, *Drosophila*, etc.) generated at UR
 - Human subjects
 - Additional experiments not routinely performed at UR (see [New PI Information](#)).
- At UR, human pathogens, or materials handled at BSL2 or higher (including human or primate blood, body fluids, tissues, cells/[cell lines](#) used or stored by non-clinical research labs/staff)



How to get IBC approval:

1. Personnel directing or performing lab work complete EH&S [Laboratory Safety Training](#).
2. PI submits consolidated [form](#) (or separate forms: LAB/L, Project/G or HS, +/- viral vector/VV)
3. EH&S performs a lab inspection; verifies Training and [Lab Safety Checklists](#) for all personnel.
4. IBC reviews protocols, assigns biosafety levels, confirms lab has been inspected and personnel are trained, then approves protocol. Biosafety Officer sends approval letter(s).

For more information:

- [IBC web pages, IBC Registration Forms, UR Biosafety Requirements and Resources](#)
- IBC Coordinator ddouglass@safety.rochester.edu, Biosafety Officer srosen22@safety.rochester.edu

Additional approvals or instructions are required for:

- Shipping, transporting biohazards, some biologicals, dry ice – [Shipping policy](#)/training
- Animals - [University Committee on Animal Resources](#) (no chem/bio/rad in vivo until EH&S sends risk letter and PI submits [Notification of Intended Use of ABSL1 or 2 Agents in the Vivarium](#)).
- Human subjects - [Research Subjects Review Board](#) (exempt? see [Exempt Status Determination](#)).
- [Chematix](#)/UR's Chemical Management System (Inventory, Waste, Safety Data Sheets)
- Lasers - [Laser Safety Program](#)
- OSHA recognized carcinogens - [Chemical Hygiene Plan](#), Chemical Safety Officer in EH&S
- Radioactive materials or isotopes - Radiation Safety Unit
- Additional listed on [Office of Research and Project Administration](#)'s, [ORPA Sign Off Form](#)



University of Rochester

Institutional Biosafety Committee

11/12/20



Welcome to the University of Rochester!

As you are a vital part of research at the University of Rochester, let me take this time to introduce you to the functions of the Institutional Biosafety Committee (IBC) and your role with the IB as you conduct your research.

As required by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), the University of Rochester Institutional Biosafety Committee (UR/IBC) reviews and approves all research (*regardless of funding source*) with biohazardous agents and recombinant or synthetic nucleic acid molecules at the University of Rochester. Approval is required *prior* to starting work.

- If an experiment covered by the NIH Guidelines is performed without IBC approval, we are required to report a '[violation](#)' of the Guidelines to NIH (regardless of funding source).

The UR IBC is a University-wide committee responsible for reviewing and approving recombinant or synthetic nucleic acid and biohazard research projects in fulfillment of its mission. The committee is composed of faculty investigators with expertise in recombinant (and synthetic) nucleic acids and biohazard research, staff from Environmental Health & Safety and non-affiliated or community members.

In the pages to follow, you will see how to seek IBC approval and how to conduct your research in accordance with the UR IBC guidelines.

Thank you and the IBC wishes you much success in your research endeavors!



Contacts

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IBC and Laboratory Safety Unit
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IBC Approval Required for Experiments Involving:

- Organisms or materials handled at Biosafety Level 2 or higher (including human or nonhuman primate blood, body fluids, tissues, cells/[cell lines](#) used or stored by non-clinical research labs or non-clinical staff)
- Experiments covered by the [NIH Guidelines](#), *regardless of funding source* (noncompliance can result in the suspension, limitation, or termination of all NIH funds for recombinant or synthetic nucleic acid molecule research per Section 1-D)
 - Recombinant infectious agents if the wild-type or modified version may cause disease in people (healthy or immune suppressed), animals or plants
 - Viral vectors (including commercial) or additional inserts
 - Plasmids or additional inserts to express or silence genes in *E. coli*, cells, animals, etc.
 - Recombinant cells administered to animals
 - Transgenic animals generated by the lab (e.g. *Drosophila*) or using UR's Mouse Genome Editing Resource, with special attention to techniques that may generate gene drives
 - Human subjects
- ❖ **Note: Toxins, other than Select Agent Toxins, are covered under the Chemical Hygiene Plan and do not require IBC approval.**



IBC Approval Also Required for:

Not commonly performed at the University - allow extra time for review.

- Possession of CDC or USDA-regulated [Select Agents](#) or Toxins that have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products)
- Experiments involving high risk influenza viruses (NIH Guidelines [Section III-D-7](#))
- The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture (NIH Guidelines [Section III-A](#))
- Cloning/expression of toxins lethal for vertebrates at an LD₅₀ of less than 100 nanograms per kilogram body weight (e.g. botulinum toxins, tetanus toxins, diphtheria toxin, shigella dysenteriae neurotoxin, NIH Guidelines [Section III-B](#))
- Experiments involving genetically modified plants, infectious diseases for plants (or vectors for disease) (NIH Guidelines [Section III-D-5](#), [Section III-E-2](#), USDA)
- Experiments involving recombinant or synthetic nucleic acids in more than 10 liters of culture (NIH Guidelines [Section III-D-6](#))



IBC Registration Process

Forms are available at <http://www.safety.rochester.edu/homepages/ibchome.html>

- UR's IBC uses a multi-form system. For new Principal Investigators, these forms are provided as a single registration document. After the initial registration, each form will be provided as a separate document for easier updating.
 - The LAB/L form, one per Principal Investigator, provides the IBC and Environmental Health & Safety (EH&S) lab-level information about where biological agents and materials are used and stored, engineering controls (aerosol containment equipment), and work practice controls (disinfection practices, medical surveillance).
 - The G Form describes experiments. After the initial registration, Principal Investigators may choose to have one G Form for each grant/project or UCAR (animal protocol), or consolidate their projects onto a single G Form, whichever works best for the researcher.
 - The VV Form provides additional information for viral vectors and recombinant viruses, with each virus type on a separate form [i.e. one for all adenovirus vectors (rAdV-), a separate one for all lentivirus vectors (rLV-), etc.] If you are using more than one virus type, additional VV forms are available on the IBC web page.
- Human Subjects Study Registration Form (HS form) and Human Subjects Research (Pandemic Respiratory Aerosols & Droplets - HSP form) also available. Use in place of G form, if applicable



Additional Information

Biological materials	IBC form/ section	Who regulates	Additional information
Infectious agents (including recombinant) if the wild-type or modified version may cause disease in people (healthy or immune suppressed), animals or plants	G form: B, C, E, I	CDC , USDA NIH Guidelines Section III-D-1 , Section III-D-4	Import or export permits may also be required (CDC, USDA, DOC)
Viral vectors (including commercial)	G form: C, E, I VV form	NIH Guidelines Section III-D-1 , Section III-D-3 , Section III-D-4 , Section III-E-1	University guidelines for viral vectors NIH - lentivirus vectors
Materials handled at Biosafety Level 2 or higher (including human or nonhuman primate blood, body fluids, tissues, cells/ cell lines used or stored by non-clinical research labs or non-clinical staff)	G form: D, I	CDC ; OSHA (if human)	Import permits may also be required (CDC, USDA, CITES)
Plasmids used to express or silence genes in <i>E. coli</i> , cells, animals, etc.	G form: E, I	NIH Guidelines Section III-D-4 , Section III-D-2	Naked siRNA or oligonucleotides are exempt if in non-replicative form



Additional Information

Biological materials	IBC form/ section	Who regulates	Additional information
Recombinant cells administered to animals	G form: I	NIH Guidelines Section III-D-4	
Transgenic animals generated by the lab (e.g. Drosophila) or using UR's Mouse Genome Editing Resource, with special attention to techniques that may generate gene drives	G form: J	NIH Guidelines Section III-D-4 , Section III-E-3	Breeding most transgenic rodents is exempt (see G form for specifics)
<p>Human clinical studies</p> <ol style="list-style-type: none"> 1. Introducing infectious agents or genetically engineered micro-organisms into human subjects (including live vaccines if they are experimental in nature and/or not FDA-approved for use in the specific study population) with or without specimen analysis 2. Introducing recombinant or synthetic nucleic acid molecules (plasmids, gene transfer vectors, viral vectors, etc.), or cells that have been treated with recombinant or synthetic nucleic acid molecules into human subjects with or without specimen analysis. 	<p>HS form</p> <p>G form if only performing specimen analysis</p>	NIH Guidelines Section III-C	May require Recombinant DNA Advisory Committee (RAC, NIH) review prior to IBC approval (see HS form instructions for specifics)



Lab Inspection

Before the IBC reviews your project, your lab requires inspection. To prepare, please visit <http://www.safety.rochester.edu/labbiosafe/bsl2certification.html>.

- All relevant vaccines must be offered PRIOR to the start of any work. Contact University Health Service (275-2662) to schedule appointments.

- For persons working with human cells or fluids, a copy of the Hepatitis B declination form can be found at: <http://www.safety.rochester.edu/ibc/BBPResource.html>

- Each person working in the lab needs to review the lab-specific biosafety manual and sign the lab safety compliance checklist (found on the last page of the manual). This manual will be reviewed during the inspection.

- Each person working in the lab or supervising lab work must also take online Laboratory Safety Training (and then annually thereafter) in MyPath. See Link to: [Laboratory Safety Training](#).



Shipping Training for Biologicals and Dry Ice

- University faculty, staff, and students who wish to ship (or transport in their personal vehicle) non-exempt biological materials must take training every two years.
 - For the online course-[Shipping Biologicals Training in MyPath](#).
 - For the Shipping policy and user-friendly manual version (companion to training):
<https://secure1.rochester.edu/safety/restricted/ShippingBiologicalMaterials.html> (NetID logon)
- The International Air Transport Association (IATA) and the US Department of Transportation (DOT) regulate shipments containing 'Dangerous Goods' and require proper packaging, labeling, and training.
 - Infectious agents
 - Genetically modified organisms or microorganisms
 - Patient specimens
 - Biological products
- Violators are subject to fines and criminal prosecution.
 - Note: Hand-carrying biological materials when traveling (for example, in a vial in your pocket or in your luggage) is strictly prohibited.
- Permits from CDC, USDA, USFW, CITES or the DOC may also be required.



LASTLY...

- Every time you receive an IBC approval letter, please verify that all of your experiments have been approved.
- Please visit the IBC homepage:
<http://www.safety.rochester.edu/homepages/ibchome.html>

Everything you need to know about the IBC is available to you here. Please call our office if you have any questions. We are here to help!

- Additional resources:
 - [UR Biosafety Requirements and Resources](#)
 - [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](#)
 - [5th edition of CDC/NIH “Biosafety in Microbiological and Biomedical Laboratories”](#)

