INTRAMURAL CORRESPONDENCE

TO: Chairs, Directors, Departmental Administrators, and Principal Investigators
FROM: Robert Passalugo, MS, CIH
Manager EH&S’s Laboratory Safety Unit
DATE: December 29, 2016
SUBJECT: Information for New PIs in Research Laboratories

Because of injuries and deaths that have occurred at various college laboratories in the United States, the UofR’s EH&S Laboratory Safety Unit was organized in 2014. The Lab Safety Unit consolidates resources and provides a unified approach toward health and safety issues for our research lab personnel.

The Laboratory Safety Unit’s overall mission is to provide a safe and healthy workplace for those working in our University's laboratories. The Unit’s major activities include:

- Evaluating the physical, chemical, and biological hazards present in laboratory locations.
- Providing required programs/plans to comply with OSHA and other state/federal regulators.
- Acting on behalf of the University for NIH/CDC/USDA required activities through the Institutional Biosafety Committee.
- Developing applicable training programs for laboratory personnel.
- Inspecting all laboratory locations to ensure compliance to regulations/codes.
- Providing documents and guidance to lab personnel to minimize hazards in laboratories.
- Responding to laboratory spills and other emergencies.

Please share this document with new PIs so they are aware of the assistance we can provide. We recognize that the PI is ultimately responsible for health/safety in their labs and are here to help. Please visit our web site at http://www.safety.rochester.edu/homepages/labsafhome.html for all the documents you may need to maintain a high level of safety in your laboratory spaces.

- Laboratory Safety Manager:
  Robert Passalugo, MS, CIH,
  Chemical Hygiene Officer, Research Laser Safety Officer
- Institutional Biosafety Officer:
  Sonia Rosenberger, DVM, MSOH
- Administrative Assistant for the Laboratory Safety Unit:
  Donna Douglass, IBC Program Coordinator
- Laboratory Safety Specialists/Inspectors:
  Carolyn Place, BS
  Mary Jo Valenti, BA
  James Smahol, BS

If you anticipate working with biological materials, please read the accompanying memo from the Chair of the IBC for requirements to be observed for you to be in compliance with the NIH: http://www.safety.rochester.edu/ibc/pdf/NewHireInformationalPacket.pdf.

If you have any questions, please feel free to contact any of us listed above by email or phone 275-3241.
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.
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.html”*
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 IBC 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 DNA and biohazard research, staff from Environmental Health & Safety and non-affiliated or community members.

In the pages to follow, you will see a DRAFT of the registration process for management of your lab and to conduct your research in accordance with the UR/IBC guidelines.

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

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IBC Approval Required for Experiments Involving:

- Using recombinant infectious agents if the wild-type or modified version may cause disease in people (healthy or immune suppressed), animals or plants

- Generating viral vectors or using viral vectors (including those acquired commercially or from another lab) to express genes in cells or animals

- Use or produce biohazardous organisms or materials handled at BSL2 or higher (including human or nonhuman primate blood, body fluids, tissues, cells or cell lines, if handled or stored in a non-clinical research lab or by non-clinical staff)

- Using plasmids to express genes in cells, animals or nonpathogenic host-vectors systems like *E. coli* (or other nonpathogenic bacteria or “lower eukaryotes”)

- Administering recombinant cells to animals

- Generating transgenic rodents or other animals (e.g. *Drosophila*); breeding most transgenic rodents exempt after 2011

- Human clinical studies with vaccines or treatments that include infectious agents or recombinant or synthetic nucleic acids

- Performing human clinical studies with vaccines or treatments that include recombinant or synthetic nucleic acids (e.g. Plasmids, infectious agents containing recombinant or synthetic nucleic acids, gene therapy)

- **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 LD$_{50}$ 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](http://www.safety.rochester.edu/homepages/ibchome.html)

- **The project registration form (G-form)**
  - Use this form to describe the research being performed. You may put more than one project on a G: form, or complete a separate G: form for each new project.

- **The Lab Registration Form (L-form)**
  - Use this form to list all of the biohazards in your possession and provide the IBC with containment and work practice information (vaccines offered, aerosol control, disinfectants used, etc.)

- **The Viral Vector Registration Form (VV form) – if applicable**
  - Use this form to provide details on the viral vectors you’re using (recombinant viruses used to deliver or transport desired inserts into cells for the purposes of insert expression).

- **The Human Subjects Study Registration Form (HS form)**
## Additional Information

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<td>Experiments involving infectious agents that can cause disease in people (healthy or immune suppressed) or animals</td>
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<td>VV form</td>
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<td>Experiments involving human or nonhuman primate blood, body fluids, tissues or cells (including cell lines), or cells/cell lines that may contain an infectious agent</td>
<td>G form: D</td>
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<td>Import permits may also be required (CDC, USDA, CITES)</td>
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<td>Using plasmids to express genes in animals or in <em>E. coli</em> (or other nonpathogenic bacteria or “lower eukaryotes”)</td>
<td>G form: E, I</td>
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<td>Naked siRNA or oligonucleotides are exempt (cannot replicate)</td>
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<td>Generating transgenic rodents</td>
<td>G form: I</td>
<td>NIH Guidelines Section III-E-3</td>
<td>Exempt since 2011: Breeding transgenic rodents</td>
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<td>- housed at BSL1, and</td>
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<td>- do not contain more than ½ the genome of any eukaryotic virus, and</td>
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<td>- do not possess a transgene under the control of a gammaretroviral LTR (like MMLV)</td>
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<td>Human clinical studies with vaccines or treatments that</td>
<td>HS or G form</td>
<td>NIH Guidelines Section III-C</td>
<td>Also requires Recombinant DNA Advisory Committee (RAC, NIH) review prior to IBC approval</td>
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<td>plasmids, infectious agents containing recombinant or</td>
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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 Services (x5-4955) 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 either MyPath or Blackboard-Learn. Link to: Laboratory Safety Training.
  - For volunteers and non-UR employees, set up a ‘basic account in Blackboard Learn at the link above to Laboratory Safety Training.
  - For non-UR personnel, since their training is not logged by HRMS, send the certificate (including the PI’s name written on the certificate) to the IBC office.
Shipping Training for Biologicals and Dry Ice

- University faculty, staff, and students who wish to ship biological materials or transport them in their personal vehicle must complete training every two years. For the online course - Shipping Biologicals Training in MyPath.

- 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.

- For additional assistance before you ship:
  - https://secure1.rochester.edu/safety/restricted/ShippingBiologicalMaterials.html (NetID logon)
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!

- CDC / NIH Biosafety in Microbiological and Biomedical Laboratories - http://www.cdc.gov/biosafety/publications/bmbl5/index.htm
- Select Agents - http://www.selectagents.gov/
- Biosafety guides from the CDC - http://www.cdc.gov/biosafety/

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