FAQs about Biosafety and Research Registration at Binghamton University

Q. Why do I have to register my research protocol?
An initiative led by the CDC and the NIH in 1976 resulted in the acceptance and use of national biosafety guidelines for research. As part of a commitment to provide a healthy and safe learning and research environment, Binghamton University follows these guidelines.

The Biosafety Officer and the Institutional Biosafety Committee (IBC) are charged to review, approve, and maintain documentation on all protocols involving recombinant DNA and other potentially hazardous biological materials including animal and plant pathogens, human cell lines and tissues, toxins, viral vectors, carcinogens and the use of transgenic organisms. Registration of research protocols with the IBC are used to determine the appropriate Biosafety level designation for each lab. This oversight ensures that the practices and containment are appropriate for the materials and procedures that are used in a lab

Q. What type of research must be registered with the IBC at Binghamton University?
All research involving recombinant DNA and other potentially hazardous materials must be registered; this includes research classified as either Biosafety Level 1 (BSL1) or Biosafety Level 2 (BSL2).
*Note: At this time, Binghamton University does not allow research to be conducted at Biosafety Level 3 (BSL 3) or above.

Experiments involving the following agents and materials must be registered:

- Recombinant DNA molecules, including viral vectors
- Naturally occurring or engineered microorganisms that may cause disease in humans, animals or plants, including those considered low risk to healthy humans and that are contained at Biosafety Level 1 (BSL1)
- Materials potentially containing human pathogens (e.g. unfixed human specimens, human blood, blood components)
- Human or mammalian (including non-human primate) cell lines, including well-established cell lines, human embryonic stem cells, and pluripotent cells and their derivatives.
- Toxins derived from plants, animals or microorganisms that will have adverse effects in humans or animals.
- Select Agents - those agents and toxins that have been determined by the federal government to have the potential to pose a severe threat to public health and safety and are under special restrictions as defined by the CDC and the USDA.
- De novo generation of transgenic animals and plants (using recombinant DNA technology to add foreign DNA or subtract a portion of the organism's genome)
- The use of carcinogens

Q. OK, so what exactly does registering with the IBC mean?
Depending upon the biological material being used and the type of research being conducted, registration can be as simple as completion of the Biosafety Protocol form in PACS, our online electronic submission system for Biosafety Level 1 (BSL1) microorganisms and materials, such as *E. coli* K12 and many plasmid vectors classified as "exempt" by the NIH Guidelines.
This protocol form, along with some additional information as requested, is also used for any research that involves Biosafety Level 2 (BSL2) agents and materials, such as *Salmonella*, human cells and tissues and lentiviral vectors. Registration using BSL2 agents and materials requires review and approval by the IBC.

Q. I do not use recombinant DNA, human cells or infectious organisms. Do I have to register?
Maybe. It may be that the wildlife you have been working with for ten years is now infected with a zoonotic, infectious agent that would require you to use additional safeguards. Or it may be that the NIH or CDC guidelines have been updated and/or reinterpreted. You should register your research in PACS with the IBC. If your research is deemed EXEPMT, you only need to register one time, unless changes to your research results in the need for a review by the IBC. In that case, you can update the form by submitting an amendment.

Q. I work with mouse tissue culture and mouse gene transfections. Why do I have to register exempt work?
All recombinant DNA research even "exempt" work requires registration.

Q. If I am working only with biohazardous materials, such as human cell lines or toxins, and not with recombinant DNA, do I need to register my project with the IBC?
Yes. The IBC reviews and approves all research involving biohazardous materials and work that requires Biosafety Level 2 containment. Any work with unfixed human cells or tissue culture is considered to be "other potentially infectious material (OPIM)" as per the OSHA Bloodborne Pathogens Standard. This requires that all personnel complete OSHA Bloodborne Pathogen training offered by the Biosafety Officer and should show proof of the Hepatitis B immunization. Environmental Health and Safety can provide further lab training for your researchers and students.

Q. I work with Drosophila and create mutants of Drosophila with P element-mediated transformation. Do I have to complete the IBC form?
Yes. Whether this research is exempt or requires IBC review and approval depends upon the genes being introduced into the Drosophila genome.

Q. I only perform transgenic research in *Arabidopsis.* Do I have to register?
Yes. You must register with the IBC and comply with the NIH, CDC and USDA guidelines and regulations for containment of transgenic plant and plant materials.

Q. I receive no funding from the NIH or from any external source. Do I have to register or notify the IBC of my research?
Yes. Registration with the IBC is based on the biological materials used in your experiments, not on funding. An institution must follow the NIH Guidelines if it receives any funding from the NIH for research involving recombinant or synthetic nucleic acid molecules. Even if only one research project involving recombinant or synthetic nucleic acid molecules at an institution benefits from NIH support, all such projects conducted at or sponsored by that institution must comply with the NIH Guidelines. Also, adherence to the NIH Guidelines may be a condition of support from other federal agencies, or even private funders of research. Finally, regardless of NIH funding, institutions may be subject to local ordinances, federal or state regulations, or agency guidelines that require compliance with the NIH Guideline. We adhere to high standards of safety in conducting recombinant or synthetic nucleic acid research.

Q. I receive funding from NSF and not from NIH. Do I have to register my research?
Yes. The NSF expects all research performed by NSF grantees that falls within the scope of the NIH Guidelines should comply with the Guidelines (NSF Awards and Administration Guide Section VI B 2b).

Q. How do I find out what Biosafety level I am to use for particular materials?

All research deemed non-exempt by the IBC is required to be performed using BSL-2 laboratory practices unless otherwise specifically stated. Albeit, there are a number of resources that may be useful in determining what biosafety level to use:

- Biosafety in Microbiological and Biomedical Research Laboratories (the BMBL) from

the Centers for Disease Control and Prevention (CDC)
http://www.cdc.gov/biosafety/publications/bmbl5/

- The NIH Guidelines for Research Involving Recombinant and Synthetic DNA Molecules (the NIH Guidelines) from the National Institutes of Health (NIH)
http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

- The American Biological Safety Association (ABSA)
https://my.absa.org/tiki- index.php?page=Riskgroups

- The US Dept. of Agriculture and the Animal and Plant Health Inspection Service - USDA/APHIS http://www.aphis.usda.gov

- Select Agent Regulations (42 CFR 73) or USDA (9 CFR 121)
http://www.selectagents.gov/select agents and Toxinslist.html

Binghamton University Biosafety Officer Kelly Donovan is available to help you determine your appropriate Biosafety Level and can be reached at 607-777-6834 or at donovan@binghamton.edu.

Q. How do I determine if my research is IBC exempt?
Determination of whether a study is exempt from IBC oversight can only be made by the IBC. A protocol must be submitted to the IBC through the PACS system. The Biological Safety officer and the IBC Chair will review the protocol and determine the study's exemption status. Regardless of a studies exemption status, any change in material use, procedure or study staff must be reported to the IBC by submitting a protocol amendment through PACS. All active studies are reviewed annually by the IBC, regardless of exemption status. It is the PI's responsibility to submit a continuing review through PACS prior to the protocol's annual deadline; the deadlines for submission is always on the anniversary of the protocols initial approval date.

Q. How do I know what the safety and containment requirements are for Biosafety Level 2 research?
The standards for research laboratories are published by the Centers for Disease Control and Prevention in the "Biosafety in Microbiological and Biomedical Laboratories" (BMBL) and by the NIH in the NIH Guidelines Appendix G. In addition, PIs are responsible for ensuring that new personnel are properly trained in accordance with the IBC Policy on Biosafety Training requirements. All faculty and staff working on an IBC registered protocol even if deemed exempt are required to complete the ***Initial Biosafety Training*** course in CITI.

Q. I have an active IBC approval for recombinant work in my lab. Recently I submitted a new research proposal. Do I have to submit a new registration or can I just modify the current protocol?
It depends. IBC approval of a registration covers only the recombinant DNA activities and biological materials listed on the BSL2 Biosafety PACS submission. The Annual Renewal and Revision may be submitted when changes are not considered to be substantial enough to require IBC review and approval. You will be required to submit a new registration if the research project involves substantial changes to the currently approved protocol.

Q. I received IBC approval in the past for my recombinant DNA molecule use. Does this approval expire?
Yes. IBC approval of research is not indefinite. IBC approved research is good for three (3) years and does require Continuing Review annually.

Q. Will my laboratory be inspected?
Yes. The Biosafety Officer is responsible for conducting periodic laboratory audits to verify biosafety practices and to compliance with all regulations. In addition, laboratories may be subject to inspection

by federal, state, and local regulatory agencies as well as funding and accrediting agencies.

Q. Can I amend the research registration after it is approved?
Yes, following initial IBC approval, you may submit an Amendment in PACS to reflect changes (i.e. rooms, experiments, personnel or biological agents). Substantive modifications to research registrations involving the addition of new biological agents (e.g. microorganisms, biotoxins, human or non-human primate derived materials) or experiments (e.g. recombinant DNA experimentation subject to NIH guidelines, significantly increased volumes or concentration of cultures, or procedures involving increased risk) may require the submission of a new research registration and IBC approval.

Q. What is the process to terminate my research?
To terminate the protocol in PACS, contact Stephen Kamper, Research Compliance Coordinator at (607) 777-3822 or via email at skamper@binghamton.edu if you should need guidance.