

## FAQs about Biosafety and Research Registration at F&M

### **Q. Why do I have to register my research protocol?**

An initiative led by the CDC and the NIH has led to the acceptance and use of national biosafety guidelines for research. As part of a commitment to providing a healthy and safe learning and research environment, Franklin and Marshall College intends to be in compliance with these guidelines.

Noncompliance with these guidelines can result in funding difficulties with the federal government that can affect all federally funded biological science research at F&M.

The Biosafety Officer and the Institutional Biosafety Committee (IBC) have been 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 will be used to determine the appropriate Biosafety level designation for each lab. This 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?**

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).

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 BSL1 Biosafety Review Form. This is the “short” form and should be used for Biosafety Level 1 (BSL1) microorganisms and materials, such as *E. coli* K12 and many plasmid vectors. This form may be used for any research that is classified as “exempt” by the NIH Guidelines.

Alternatively, research registration may entail submission of the BSL2 Biosafety Review form; this is the “long” form and should be 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 the BSL2 Biosafety Review form requires review and approval by the IBC.

### **Q. I do not use recombinant DNA, human cells or infectious organisms. Do I have to register?**

Yes, 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 Guidelines and the BMBL have been updated and/or reinterpreted. You should use the BSL1 Biosafety Review form. If you answer “no” to every question, you only need to file the form one time, unless changes to your research projects would result in a “yes” answer to any question on the form. In that case, you would need to update the form.

**Q. I know that some recombinant DNA work involving agents such as *E. coli* K12, plasmids and *Saccharomyces* is exempt from the NIH Guidelines. How do I know if my recombinant DNA molecule use is exempt or not?**

Your answer can be found by reviewing Section III of the NIH Guidelines. Exempt experiments are covered under Section III-F. If your recombinant DNA molecule use does not fall within the exempt experiments, you should review Section III in whole to determine where your research falls for registration purposes.

**Q. If my recombinant DNA molecule use falls into the exempt category, do I still need to register the project with the IBC?**

Yes, The IBC is charged with registering ALL recombinant DNA research even “exempt” work. The compliance required of you depends upon which agents you are using and what genes are being manipulated. Periodically, the NIH Guidelines and the BMBL are updated and/or reinterpreted in a way that may result in a change in the status of your work.

Most work with exempt agents or materials at BSL-1 does not require review and approval by the IBC and can simply be registered using the BSL1 Biosafety Review Form.

Registration is a benefit for the PI because funding sources will often ask for documentation of IBC review regardless of the exempt status of the recombinant DNA molecule use. In some cases, the funding source will not release funds without this documentation.

**Q. I work with mouse tissue culture and mouse gene transfections. Why do I have to register exempt work?**

The IBC is charged with registering ALL recombinant DNA research even “exempt” work. Whether this research requires full IBC review and approval depends upon the genes being introduced into the tissue culture. The researcher and the Biosafety Officer will make this decision with the IBC, if necessary.

**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 Bloodborne Pathogen training offered by the Biosafety Officer and are offered the opportunity to receive the Hepatitis B immunization. The Exposure Control Plan can be reviewed at the F&M Environmental Health and Safety web page.

**Q. I work with *Drosophila* and create mutants of *Drosophila* with P element-mediated transformation. Do I have to complete the IBC form?**

Yes, you must register with the IBC. Whether this research requires IBC review and approval depends upon the genes being introduced into the *Drosophila* genome. The researcher, the Biosafety Officer and/or the IBC will determine whether full review and approval are required.

**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. The intent of registration is to ensure the safe handling, use and storage of potentially biohazardous materials.

**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 2).

**Q. How do I find out what Biosafety level I am supposed to use for the material that I work with?**

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](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html)
- The American Biological Safety Association (ABSA) <http://www.absa.org/riskgroups/index.html>
- 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\\_Toxins\\_list.html](http://www.selectagents.gov/select_agents_and_Toxins_list.html)

The Biosafety Officer is also available to help you determine your appropriate Biosafety Level.

**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 Level 2 Training Requirements.

**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 Review form. The Annual Renewal and Revision - BSL2 Biosafety Review Form 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. For labs with BSL1 designation, the BSL1 Biosafety Review form must be updated and resubmitted annually.

For labs with BSL2 designation the Annual Renewal and Revision form must be updated annually.

This form should also be submitted whenever any changes (such as the addition or removal of infectious agents, viral vectors, human cell lines, etc.) to your research registration are made. Every 3 years, the BSL2 Biosafety Review form must be resubmitted for IBC review and approval.

**Q. Will my laboratory be inspected?**

Yes. The Biosafety Officer is responsible for conducting periodic laboratory audits. These are an opportunity to review biosafety practices and to verify 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 the Annual Renewal and Revision - BSL2 Biosafety Review Form to reflect changes in rooms, experiments 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.

**Termination** of experiments can be registered using the Research Registration Renewal/Revision form.

**Helpful Links**

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](http://oba.od.nih.gov/rdna/nih_guidelines_oba.html)

The American Biological Safety Association (ABSA) <http://www.absa.org/riskgroups/index.html>

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\\_Toxins\\_list.html](http://www.selectagents.gov/select_agents_and_Toxins_list.html)