# Bryn Mawr College Institutional Biosafety Committee (IBC)
# Instructions for Protocol Registration Form

The Bryn Mawr College IBC is responsible for ensuring that all activity involving recombinant DNA (rDNA), synthetic DNA, or other biohazards that is conducted or sponsored by the College complies with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html), which must be consulted when filling out the Protocol Registration Form.

rDNA or synthetic DNA is defined by the NIH as:

> (i) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e., recombinant nucleic acids;
>
> (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids; or
>
> (iii) molecules that result from the replication of those described in (i) or (ii) above.

All activities involving rDNA or other biohazards must be registered with and, if necessary, approved by the IBC. Certain types of research are exempt from the IBC approval process and will be recognized as such via the registration process. Please submit the Protocol Registration Form at least one week prior to the IBC meeting and prior to the initiation of your project.

**Project Status**

Indicate whether the PI is submitting protocols for a new project, is proposing significant changes to a previously approved project, or requires rereview of a continuing project because the approval window of 3 years (or shorter interval if appropriate) will soon expire.

**Risk Groups and Biosafety Levels**

For definitions of Risk Groups and Biosafety Levels, see Bryn Mawr College Institutional Biosafety Committee Policy, Appendix II.

RG2, RG3, and RG4 work and work falling under Sections III-A–III-E are not exempt from NIH Guidelines and require a full review by the IBC.

RG1 work and work falling under Section III-F, Appendix A, or Appendix C are exempt from NIH Guidelines but still require registration of the project with the IBC.

If applying for exemption, list the relevant subsections in Section III-F and/or Appendices A and C that apply to your research.

**Meaning of Signature on Protocol Registration Form**

If the PI applies for an exemption from IBC review, the PI's signature certifies that the following conditions apply to the proposed activities:

- The study does not involve the deliberate transfer of a drug-resistant trait to microorganisms that are not known to acquire the trait naturally if such acquisition compromises the ability to control disease agents in humans, veterinary medicine, or agriculture.
- The study does not involve cloning toxin molecules lethal for vertebrates at an $LD_{50}$ of less

than 100 nanograms per kilogram body weight.
- The study does not involve the deliberate transfer of rDNA or other biohazards into one or more human subjects.
- The study does not use RG3, RG4, or restricted agents as host-vector systems.
- The study does not clone DNA from RG3, RG4, or restricted agents into nonpathogenic prokaryotic or lower eukaryotic host-vector systems.
- The study does not involve the use of infectious or defective DNA or RNA viruses in the presence of a helper virus in tissue culture systems.
- The study does not involve whole animals or whole plants.
- The study does not involve more than 10 liters of culture.
- The study does not involve influenza viruses generated by rDNA.
- The study does not involve the formation of rDNA containing more than 2/3 of the genome of any eukaryotic virus.
- The study does not involve generation of transgenic animals or plants.

By signing the Protocol Registration Form, the PI certifies that:
- I have familiarized myself with the federal regulations governing research involving rDNA and other biohazards as compiled in the NIH Guidelines.
- I have disclosed the nature of the work done with rDNA and/or other biohazards in my laboratory and attest that it is in the category that has been declared on the form.
- I will not conduct experiments involving rDNA and/or other biohazards that are subject to regulation by NIH Guidelines without the authorizations mandated therein.
- I will not begin or modify activities covered under Sections III-A through III-D without first securing IBC approval and, where necessary, NIH approval.
- I will not begin or modify activities covered under Sections III-E and III-F without first submitting a Protocol Registration Form to the IBC.
- I will submit a separate Continuing Review Form to the IBC every year that the protocols are approved.
- I have read and understand my responsibilities as Principal Investigator, as outlined in the NIH Guidelines Section IV-B-7 and in the policies of the Bryn Mawr College IBC, and will comply with these responsibilities.
- The information provided therein is accurate to the best of my knowledge. I also understand that, should I use the project described on the form as a basis for a funding proposal (intramural or extramural), it is my responsibility to ensure that the description of the work in the funding proposal is identical in principle to that contained in the Protocol Registration Form.