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

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) must be consulted when filling out this form.

Principal Investigator :	
Department :	
Email :	
Phone :	
Laboratory location (building and room) **:**	
Funding agency (if applicable) **:**	
Project title/Course number :	

List personnel participating in this project. Include title/position (i.e. student, staff).

Provide a brief summary (3–5 sentences) of your research goals and overview of the proposed use of biological materials, specifically referencing rsNA materials and/or biohazards to be used.

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

Identify which of the following you are using and complete the corresponding section of this form.

☐ Recombinant or Synthetic Nucleic Acid Materials: Section A

☐ Microorganisms: Section B

☐ Human Materials: Section C

☐ Animals and/or materials (vertebrate and invertebrate): Section D

☐ Plants: Section E

Will you be shipping biological materials and/or dry ice?

☐ No ☐ Yes

Note: Section F (Containment plan) must be completed for all submissions

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

Section A: Recombinant or Synthetic Nucleic Acid Molecules

1. Under which section of the NIH Guidelines does this work fall?

III-A: Experiments that Require NIH Director Approval and Institutional Biosafety Committee Approval Before Initiation

- ☐ A-1: Major Actions
- ☐ A-1-a: Deliberate transfer of drug resistance trait to microorganisms that are not known to acquire

III-B: Experiments That Require NIH OSP and Institutional Biosafety Committee Approval Before Initiation

- ☐ B-1: Experiments Involving the Cloning of Toxin Molecules with LD50 of Less than 100 Nanograms per Kilogram Body Weight
- ☐ B-2: Experiments that have been Approved (under Section III-A-1-a) as Major Actions

III-C. Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation

- ☐ C-1: Experiments Involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants

III-D: Experiments that Require Institutional Biosafety Committee Approval Before Initiation

- ☐ D-1: Experiments Using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems
- ☐ D-2: Experiments in Which DNA From Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems
- ☐ D-3: Experiments Involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems
- ☐ D-4: Experiments Involving Whole Animals
- ☐ D-5: Experiments Involving Whole Plants
- ☐ D-6: Experiments Involving More than 10 Liters of Culture
- ☐ D-7: Experiments Involving Influenza Viruses

III-E: Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation

- ☐ E-1: Experiments Involving the Formation of Recombinant or Synthetic Nucleic Acid Molecules Containing No More than Two-Thirds of the Genome of any Eukaryotic Virus
- ☐ E-2: Experiments Involving Whole Plants
- ☐ E-3: Experiments Involving Transgenic Rodents

III-F: Exempt Experiments

- ☐ Cite section of the Guidelines under which you believe your work is exempt and describe rationale: _____

Section A: Recombinant or Synthetic Nucleic Acid Molecules (continued)

2. Are you using a Vector System? ☐ No ☐ Yes

   * If yes, please send map(s) of vector backbone to IBC

   a. Name of the vector system: _____

      ☐ Bacterial Plasmid
      ☐ Adeno-Associated Viral (AAV) vectors
      ☐ Adenoviral vectors
      ☐ Retroviral vectors (not lentivirus)
         Identify virus: _____
         Envelope tropism: ☐ Ecotropic ☐ Amphotropic
      ☐ Lentiviral vectors
      ☐ Other, describe: _____

   b. Is the material propagated in your lab?

      ☐ No ☐ Yes, specify cells or organism: _____

   c. For Viral Vectors Only:

      1. Does this vector contain > 2/3 of the viral genome? ☐ No ☐ Yes
      2. Is this vector replication competent? ☐ No ☐ Yes
      3. Is a helper virus required for replication? ☐ N/A ☐ No ☐ Yes
      4. Is this vector packaged in your lab?

         ☐ No Identify source providing vector: _____
         ☐ Yes List cell line (name, species): _____

   d. Transgenes

      1. Identify the genes being expressed by the vector.

Promoter	Gene Name	Source (genus, species)	Function of Sequence

      2. Are any of these genes from > 2/3 of the viral genome? ☐ YES ☐ NO
      3. Will a deliberate attempt be made to obtain expression of the sequence?

         ☐ No ☐ Yes

Section A: Recombinant or Synthetic Nucleic Acid Molecules (continued)

e. Target Recipient: Indicate the recipients of the rsNA material (check all that apply)

- ☐ Animal only (specify species and if mouse, strain): _____
- ☐ Cells only (specify cell type, name, and species): _____
- ☐ Modified cells into animals
  - Specify cell type, name, and species: _____
  - Specify animal species/mouse strain: _____
- ☐ Microorganism only (specify genus, species): _____
- ☐ Modified microorganism into animals
  - Specify microorganism genus, species: _____
  - Specify animal species/mouse strain: _____
- ☐ Plants (specify genus, species): _____
- ☐ Humans

---

3. Are you creating transgenic rodents? ☐ No ☐ Yes

a. Name of parent strain (i.e. C57Bl/6): _____

b. Specify the nature of the sequences being modified or inserted

Promoter	Gene Name	Source (genus, species)	Function of Sequence

c. Are any of these genes from > 2/3 of the viral genome? ☐ No ☐ Yes

d. Will a deliberate attempt be made to obtain expression of the sequence? ☐ No ☐ Yes

e. Describe the method of used to create the transgenic rodents: _____

---

4. Are you using, crossing, and/or creating transgenic non-rodent animals (drosophila, zebrafish, etc)? ☐ No ☐ Yes

   a. Name of parent strain (i.e. Drosophila melanogaster): _____

   b. Identify your use of these animals (check all that apply):

   ☐ Using existing strains Identify source: _____, send table of strains to IBC

   ☐ Crossing existing strains Identify source: _____, send table of strains to IBC

   ☐ Creating new strains

   1. Describe the method used to create the transgenic animals: _____
   2. List transgenic strains below or send table to IBC:

      _____

---

5. Biosafety Containment Level

   a. This project will be conducted at Biosafety Level (BSL): ☐ 1 ☐ 2

   b. This project will be conducted at Animal Biosafety Level (ABSL): ☐ N/A ☐ 1 ☐ 2

   c. This project will be conducted at Plant Biosafety level (P-BSL): ☐ N/A ☐ 1 ☐ 2

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

Section B: Microorganisms (Bacteria, Viruses, Fungi, Parasites)

1. Identify microorganisms in the table below. For pathogenicity, enter:

HP: Human pathogen AP: Animal Pathogen

PP: Plant Pathogen NP: Non-pathogenic

Name (genus, species)	Strain, if applicable	Pathogenicity	Risk Group

2. Biosafety Containment Level

a. This project will be conducted at Biosafety Level (BSL): ☐ 1 ☐ 2

Section C: Human blood, body fluids, tissues, cells

1. Identify the type of human material below. Include source from which you obtained the material (i.e. ATCC, collaborator at another University, donor subjects)

☐ Human blood

Source: _____

☐ Human tissue

Source: _____

Organ/tissue type: _____

State: ☐ Fixed ☐ Fresh/frozen ☐ Lysed, describe: _____

☐ Human cells

☐ Primary Cells Name/type: _____

☐ Established cell lines Name/type: _____

2. Biosafety Containment

a. This project will be conducted at Biosafety Level (BSL): ☐ 1 ☐ 2

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

Section D: Live Animals and/or Materials (includes use blood, body fluids, tissues, cells)

1. Are you using live animals? ☐ No ☐ Yes

   a. Is this work approved by the IACUC? ☐ N/A ☐ No ☐ Yes

   b. Identify type of animal:

   ☐ Nematode (genus, species): _____

   ☐ Insect (genus, species): _____

   ☐ Fish (genus, species): _____

   ☐ Rodent (genus, species): _____

   ☐ Other, describe: _____

2. Are you using materials derived from animals? ☐ No ☐ Yes

   a. Identify the type(s) of animal:

   ☐ Nematode (genus, species): _____

   ☐ Insect (genus, species): _____

   ☐ Fish (genus, species): _____

   ☐ Rodent (genus, species): _____

   ☐ Other, describe: _____

   b. Describe the type(s) of material: _____

3. Biosafety Containment Level

   a. This project will be conducted at Biosafety Level (BSL): ☐ 1 ☐ 2

   b. This project will be conducted at Animal Biosafety Level (ABSL): ☐ N/A ☐ 1 ☐ 2

Section E: Plants

1. Identify the genus, species: _____

2. Is a USDA Permit required for transport or use of these plants? ☐ No ☐ Yes

   If yes, provide permit or application number: _____

3. Biosafety Containment

   a. This project will be conducted at Plant Biosafety Level (BSL[P]): ☐ 1 ☐ 2

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

Section F: Containment Plan

Describe special precautions, including use of biosafety cabinet, PPE, and waste disposal procedures.
Outline potential risks.
Describe the emergency plan should the containment plan be unfeasible. Note: If animals must be moved, include information about secondary location and personnel involved in the move.

By signing below, I certify that the answers provided on this form are complete and accurate. I certify that all protocol activities will take place in accordance with state and federal regulations and the regulations of Bryn Mawr College.

Signature of Principal Investigator _____

Date _____

Signature of Faculty/Staff Advisor _____
(if PI is not Faculty/Staff)

Date _____

For IBC use only:

☐ Approved ☐ Request for clarifications or modifications ☐ Approval withheld ☐ Exempted

Name of IBC Chair _____

Date _____

IBC Approval Number _____