Hamilton Institutional Biosafety Committee (HIBC)
Protocol Registration Form

Principal Investigator: _____
Department: _____
Phone: Email: _____
Office Location: _____
Lab Location: _____
Project Title: _____
Date of Submission: _____

Please return completed form to Siobhan Robinson, HIBC Officer and Chair of Hamilton Institutional Biosafety Committee, 3065 Science Center, or e-mail sxrobins@hamilton.edu

General Instructions: The intent of this form is to ensure compliance with NIH/CDC guidelines for research lab biosafety and ASM for teaching lab biosafety. This form ensures that you; understand potential hazards involved in your research, have designed experiments to minimize such hazards, and have communicated these potential hazards and protective measures to anyone involved with research or lab maintenance. In some cases, it may be appropriate to combine more than one organism/experiment onto one form. If the form is clear and understandable, then a PI may feel free to add multiple experiments/organisms to this form.

Please mark which sections you will be completing

Part A: Recombinant DNA experiments. Indicate any adverse effects of the DNA, quantity of culture used, and a description of the experiment. Also provide detailed information regarding the DNA inserts, vectors and host cells being used in your rDNA system. For further information, please visit the NIH website: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

Part B: Pathogenic microorganisms. Agents capable of causing disease in immune-normal, healthy adults must be registered in Part B. These agents include organisms classified as RG-2 or higher in the latest edition of the CDC Biosafety in Microbiological and Biomedical Laboratories publication. https://www.cdc.gov/labs/BMBL.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fbiosafety%2Fpublications%2Fbmbl5%2Findex.htm **Registration is required for RG-2 or higher.**

Part C: Human blood, cell lines, tissues, or other potentially infectious materials (OPIM). These items, including established human/primate cell lines obtained from commercial sources are also included in this requirement. OPIM is material with the potential for transmission of HIV, HBV, HCV, and other blood borne diseases including tissue from animals known to be infected with any of these agents, microbial stocks and cultures, certain body fluids, unfixed human tissue, primary tissue/cell cultures and must be registered in Part C. These must be handled under RG-2 conditions as if they were primary cells or tissues. For further information, please visit the CDC website: http://www.cdc.gov/biosafety/publications/bmbl5/index.htm

Part D: Administration to animals of any of the above selections. Administration of any of the above agents to animals requires approval of the IACUC and may also require that the animals be housed in specialty cages and handled under RG-2 conditions.

Part E: Safety Measures. This section must be completed for all registrations.

Part F: Affirmation. This section must be completed for all registrations.

Part A: Recombinant DNA: Please identify the type of experiment described in this registration for by checking the appropriate category in column E.

A	B	C	D	E
If your experiment involves:	Registration w/ NIH required?	Registration w/ IBC required?	IBC must receive registration:	Experiment described on this form involves:
Cloning of DNA encoding toxin molecules lethal to vertebrates at an LD_{50} of less than 100ng/kg	Yes	Yes	Prior to initiation	
Human gene therapy	Yes	Yes	Prior to initiation	
Transfer of drug resistance to an organism not known to naturally acquire that trait, if such an acquisition could compromise ability to control the disease in humans, veterinary medicine, or agriculture	Yes	Yes	Prior to initiation	
RG 2, 3, or 4 agents as host-vector systems	No	Yes	Prior to initiation	
Cloning of DNA from RG 2, 3, or 4 microorganisms into nonpathogenic prokaryotic or lower eukaryotic host-vector systems	No	Yes	Prior to initiation	
Use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems	No	Yes	Prior to initiation	
Use of transgenic animals at RG-2 or above	No	Yes	Prior to initiation	
Use of viable rDNA modified microorganisms involving whole animals or whole plants	No	Yes	Prior to initiation	
Administration of rDNA to animals or plants	No	Yes	Prior to initiation	
More than 10L of culture	No	Yes	Prior to initiation	
Propagation and maintenance in tissue culture of rDNA containing <2/3 of the genome of any eukaryotic virus in the **demonstrable** absence of helper virus or a virus that has been shown to be non-replicating	No	Yes	At initiation	
Propagation and maintenance in tissue culture of rDNA containing a virus that has been shown to be non-replicating	No	Yes	At initiation	
Formation of rDNA containing no more than 2/3 of the genome of any eukaryotic virus	No	Yes	At initiation	
Use of transgenic animals at RG-1	No	No	n/a	
rDNA not in an organism or virus	No	No	n/a	
DNA segments from a single non-chromosomal or viral DNA source	No	No	n/a	
DNA entirely from a prokaryotic host when propagated only in that host	No	No	n/a	

DNA entirely from a prokaryotic host when transferred to another host by well-established physiological means	No	No	n/a	
DNA from a eukaryotic host when propagated only in that host or a closely related strain of the same species	No	No	n/a	
DNA segments from different species that exchange DNA by known physiological processes	No	No	n/a	

Please complete the following section to describe your experiment:

1. Does the donor rDNA, RNA, cDNA source or its vector have any recognized or anticipated pathogenic, toxigenic, or viral potential for animals, plants, or humans?
    A. If yes, explain
    B. If no, please provide a supporting reference

2. Quantity of material to be used
    A. <1L
    B. 1-10L
    C. >10L

3. Location (building name/room number) where rDNA research is to be conducted.

4. Specify the source and nature of the DNA sequence(s) to be inserted (genus, species, gene name):

5. Will the inserted gene(s) be expressed?
    A. If so, what are the gene product effects? Specifically identify any toxicity, physiological activity, allerginicity, oncogenic potential, or ability to alter the cell cycle:

6. Describe the virus, phage, and/or plasmid used for constructing your recombinants:
    C. If possible, provide a diagram or map illustrating the construct. If appropriate, include Entrez Gene nomenclature (http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=gene)

7. Identify host cell(s) or packaging cell line in which recombinant vector will be amplified.

8. Is the vector replication competent?

9. Are any viral components or sequences present?
    A. If yes, specify the nature of the viral components:

10. Does the insert contain >2/3 of a eukaryotic viral genome?

11. Is helper virus used?
    A. Specify type:

12. Is it a retrovirus?

13. What cells, tissues, animals, humans, insects, or plants will be exposed to the recombinant?

14. Will you work with transgenic animals?

15. Will human subjects be exposed to rDNA?

16. Please provide a brief description of proposed research, providing enough information to describe specific aims. Please use additional paper if necessary:

Part B: Pathogenic Microorganisms

1. Name of organism (genus, species, strain description) :
    A. Is the organism attenuated?

2. Is a toxin produced?
    A. Will you be working with the toxin?

3. Is drug resistance expressed?
    A. If so, indicate to which drugs:

4. Where (building, room number) is the organism stored?
    A. Are biohazard warning labels in use?

5. Is a stock culture prepared? If so, indicate:
    A. Total volume of stock culture
    B. Volume aliquoted per individual vial
    C. Concentration /ml individual vial
    D. Maximum volume used in an experiment

6. Is organism inactivated prior to use? a. Specific method:

7. Do you concentrate the organism in your protocol?
    A. Specific method:
        i. Centrifugation
        ii. Precipitation
        iii. Filtration
        iv. Other:

8. Does the laboratory work with human blood or blood products, unfixed human tissue, or human or other primate cells? If yes, complete Part C below.

9. Are cultures, stocks, and contaminated items decontaminated prior to disposal?
    A. Method:
        i. Autoclave
        ii. Chemical disinfectant
        iii. Other (describe):

10. Please provide a brief description of proposed research, providing enough information to describe specific aims. Use additional paper if necessary:

C: Human Cells and Tissues

Include in the following table any established human or primate ATCC cell lines and any other potentially infectious materials:

1.	2.	3.
4.	5.	6.
7.	8.	9.

1. Please provide a brief description of proposed research, providing enough information to describe specific aims. Use additional paper if necessary:

Part D: Animal Use

Will biohazardous materials listed above be administered to animals? **If YES, complete the following section. If NO, go to part E for non-animal work safety concerns**

1. What species will be exposed?

2. State the Institutional Animal Care and Use Committee active or pending
   IACUC Protocol number:

3. State the maximum volume and concentration to be administered per animal:

4. State the maximum volume and concentration to be administered per experiment:

5. On a separate page, please provide a brief description of proposed research, providing enough information to describe specific aims:

6. Animal Risk Group (ARG) required:

7. Indicate proposed route of administration
   A. Aerosol
   B. Catheter or cannula
   C. Intranasal
   D. IV , IM, IP
   E. Other (specify):

8. Will the animals be anaesthetized or tranquilized during administration? _____

9. Is the agent(s) an animal pathogen? _____

10. Is the agent(s) a human pathogen? _____

11. Is the agent(s) transmitted from animal to animal? _____

12. Is the agent(s) transmitted from animal to human? _____

13. Will the agent(s) be inactivated prior to use in animals? _____

14. Will the animals be housed in micro-isolator cages? _____

15. Will there be any special procedures or containment needed? _____
   A. Describe any special requirements:

16. Will animal work be performed in a biosafety cabinet? _____

Part E: Safety Measures

1. Indicate any engineering controls used to prevent potential contamination
    A. Containment suite (e.g. RG-2)
    B. Biocontainment animal housing (if applicable)
    C. Class II biological safety cabinet
    D. Centrifuge safety cups
    E. Other (please specify):

2. Sharps used at RG-2 and above should be minimized
    A. Will syringes, scalpels, glass, or other sharps be used?
    B. Has the research protocol been reviewed to eliminate or minimize the use of sharps where possible?
    C. Are sharps with integrated safety devices/mechanisms available and used? If so, describe the devices(type, model, brand):

3. Indicate any Personal Protective Equipment (PPE) that will be required for your work
    A. Lab coat
    B. Safety glasses
    C. Apron or rear fastening gown
    D. Bonnet or other hair cover
    E. Gloves (indicate type below)

4. Use the table below to indicate disinfectant methods per application:

	Autoclave	1/10 bleach solution	Povidone/iodine product	70% ethanol	Phenolic product	Chlorine dioxide product	Quarternary ammonium product	Other: Specify
Routine spill cleanup								
Solid Waste								
Liquid Waste								
Animal Waste								
Other: Specify								

5. PI's Assessment of Risk

A. What is the most serious adverse effect you can foresee as a result of this experiment?

B. How did you determine appropriate risk group for this procedure?

C. Please list the following information about your most recent literature search on the safety of the organisms, reagents, and experimental procedures used in this protocol

i. Date of most recent search:
ii. What database was used:
iii. What keywords were used:
iv. Please describe any pertinent safety or hazard analysis findings:

D. Is there any potential for this material to be contaminated with an organism requiring a higher risk group?

i. How would you determine if the material was contaminated with such an organism?

ii. Is your lab equipped to perform such an evaluation?

E. What was the source of this material (e.g. ATCC, colleague, other)? _____

i. Can the sender provide background information or quality control data on the material? _____

ii. Have you already obtained such documentation? _____

6. Medical surveillance (circle appropriate response)

A. Personnel have completed required safety training within the past year. (YES or NO)

B. Personnel have attended basic laboratory safety training. (YES or NO)

C. All personnel who are potentially exposed to blood, body fluids, or human cell lines have received Hepatitis B vaccine or have proven immunity. (YES or NO)

D. Additional vaccination is required for work on this project. Please specify:

E. Individuals at increased risk of susceptibility have contacted Occupational Health Services at MVHS Hospital or Hamilton College Student Health Services for counseling.

F. There is a known vaccine or therapy. Please specify:

Please list all personnel who will be working on this project, including the dates of their most recent basic Lab Safety and/or BSL2/BSL2+ additional training, if applicable. Please obtain their signature as evidence that they have been informed of potential hazards related to this project.

Name: _____ BSL2/2+ Training Date: _____

Signature: _____ Lab Safety Training Date: _____

Name: _____ BSL2/2+ Training Date:_____

Signature: _____ Lab Safety Training Date: _____

Name: _____ BSL2/2+ Training Date:_____

Signature: _____ Lab Safety Training Date: _____

Name: _____ BSL2/2+ Training Date:_____

Signature: _____ Lab Safety Training Date: _____

Part F: Affirmation

I accept responsibility for the safe conduct of work with this material. I accept responsibility for ensuring that all personnel associated with this work have received the appropriate training on the hazards and the levels of containment required to perform this research safely. I will report to Skidmore College EHS any accident or incident that results in a potentially toxic exposure to personnel or any incident releasing recombinant DNA or other potentially hazardous materials into the environment.

Principal Investigator:_____

Signature: _____

Date: _____

Grant Agency and award number, if applicable:_____