****

**Institutional Biosafety Committee (IBC)**

**Protocol Registration Form**

Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Department:

Phone: Email: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Office Location: Lab Location:

Project Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of Submission:

**Please return completed form to Loretta Greenholtz, Biosafety Officer, 437 Palamountain Hall or e-mail** **lgreenho@skidmore.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

For activities specific to the *teaching lab* environment, the American Society of Microbiology (ASM) has prepared the <https://www.asm.org/Guideline/ASM-Guidelines-for-Biosafety-in-Teaching-Laborator>.

For activities specific to the *research lab* environment, both NIH and CDC have prepared guidance documents. Blink is available to work involving Ecoli:

<https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html>,

<https://blink.ucsd.edu/safety/research-lab/biosafety/nih/e-coli.html>,

<http://www.cdc.gov/biosafety/publications/bmbl5/index.htm>

All submitted research protocol must be in adherence with these established guidelines.

**Please mark which sections of this form 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.**

 **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 LD50 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?
	1. If yes, explain
	2. If no, please provide a supporting reference
2. Quantity of material to be used
	1. <1L
	2. 1-10L
	3. >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): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	1. Will the inserted gene(s) be expressed? \_\_\_\_\_\_\_\_
	2. If so, what are the gene product effects? Specifically identify any toxicity, physiological activity, allerginicity, oncogenic potential, or ability to alter the cell cycle:
5. Describe the virus, phage, and/or plasmid used for constructing your recombinants:
6. 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? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	1. 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? \_\_\_\_\_\_\_\_\_\_\_\_
	1. 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 description of proposed research, providing enough information to describe specific aims, as well as, appropriate operational details. Please use additional paper if necessary:

**Part B: Pathogenic Microorganisms**

1. Name of organism (genus, species, strain description) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	1. Is the organism attenuated? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Is a toxin produced?
	1. Will you be working with the toxin? \_\_\_\_\_\_\_\_\_\_\_\_
3. Is drug resistance expressed?
	1. If so, indicate to which drugs \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
4. Where (building, room number) is the organism stored?
	1. Are biohazard warning labels in use? \_\_\_\_\_\_\_
5. Is a stock culture prepared? If so, indicate:
	1. Total volume of stock culture
	2. Volume aliquoted per individual vial
	3. Concentration /ml individual vial
	4. Maximum volume used in an experiment
6. Is organism inactivated prior to use?
	1. Specific method:
7. Do you concentrate the organism in your protocol?
	1. Specific method:
		1. Centrifugation
		2. Precipitation
		3. Filtration
		4. 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?
	1. Method:
		1. Autoclave
		2. Chemical disinfectant
		3. Other:
10. Please provide a description of proposed research, providing enough information to describe specific aims, as well as, appropriate operational details. 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, as well as, appropriate operational details. Use additional paper if necessary:

**Part D: Animal Use**

1. 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:

1. State the maximum volume and concentration to be administered per animal:
2. State the maximum volume and concentration to be administered per experiment:
3. State On a separate page, please provide a brief description of proposed research, providing enough information to describe specific aims:
4. *Animal* Risk Group (ARG) required:
5. Indicate proposed route of administration
	1. Aerosol
	2. Catheter or cannula
	3. Intranasal
	4. IV, IM, IP
	5. Other (specify):
6. Will the animals be anaesthetized or tranquilized during administration? \_\_\_\_\_\_\_
7. Is the agent(s) an animal pathogen? \_\_\_\_\_\_\_\_
8. Is the agent(s) a human pathogen? \_\_\_\_\_\_\_\_
9. Is the agent(s) transmitted from animal to animal? \_\_\_\_\_\_\_
10. Is the agent(s) transmitted from animal to human? \_\_\_\_\_\_\_
11. Will the agent(s) be inactivated prior to use in animals? \_\_\_\_\_\_\_
12. Will the animals be housed in micro-isolator cages? \_\_\_\_\_\_\_
13. Will there be any special procedures or containment needed? \_\_\_\_\_\_\_
	1. Describe any special requirements:
14. Will animal work be performed in a biosafety cabinet? \_\_\_\_\_\_\_\_

**Part E: Safety Measures**

1. Indicate any engineering controls used to prevent potential contamination
	1. Containment suite (e.g. RG-2)
	2. Biocontainment animal housing (if applicable)
	3. Class II biological safety cabinet
	4. Centrifuge safety cups
	5. Other (please specify):
2. Sharps used at RG-2 and above should be minimized
	1. Will syringes, scalpels, glass, or other sharps be used? \_\_\_\_\_\_\_
	2. Has the research protocol been reviewed to eliminate or minimize the use of sharps where possible? \_\_\_\_\_\_\_
	3. 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
	1. Lab coat
	2. Safety glasses
	3. Apron or rear fastening gown
	4. Bonnet or other hair cover
	5. 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 |  |  |  |  |  |  |  |  |

1. **PI’s Assessment of Risk**
	1. What is the most serious adverse effect you can foresee as a result of this experiment?
	2. How did you determine appropriate risk group for this procedure?
	3. 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
		1. Date of most recent search: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
		2. What database was used: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
		3. What keywords were used: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
		4. Please describe any pertinent safety or hazard analysis findings:
	4. Is there any potential for this material to be contaminated with an organism requiring a higher risk group? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
		1. How would you determine if the material was contaminated with such an organism?
		2. Is your lab equipped to perform such an evaluation?
	5. What was the source of this material (e.g. ATCC, colleague, other)? \_\_\_\_\_\_\_\_\_\_\_\_\_\_
		1. Can the sender provide background information or quality control data on the material? \_\_\_\_\_\_\_\_\_\_\_\_
		2. Have you already obtained such documentation? \_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. **Medical surveillance (Check all that apply)**
	1. Personnel have completed required safety training within the past year.
	2. Personnel have attended basic laboratory safety training. 
	3. All personnel who are potentially exposed to blood, body fluids, or human cell lines have received Hepatitis B vaccine or have proven immunity.
	4. Additional vaccination is required for work on this project. Please specify:
	5. Individuals at increased risk of susceptibility have contacted Occupational Health Services at Saratoga Hospital or Skidmore College Student Health Services for counseling.
	6. There is a known vaccine or therapy. Please specify:
	7. Please list all personnel who will be working on this project, including the dates of their most recent BBP/Universal Precautions (UP) and basic Lab Safety training if applicable. Please obtain their signature as evidence that they have been informed of potential hazards related to this project.

Name: CITI BPP or UP Training Date:

Signature: Lab Safety Training Date:

Name: CITI BPP or UP Training Date:

Signature: Lab Safety Training Date:

Name: CITI BPP or UP 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:

****

**IBC Approval Page**

**(For IBC Use Only)**

IBC Protocol Reg. No: Risk Group:

**Approval: Yes Yes, with modification Yes, with contingency**

**Protocol Approval Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Protocol Expiration Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Committee Determined Risk Group: \_\_\_\_\_\_\_\_\_\_\_\_**

**Signatures**

IBC Chairman:

Biological Safety Officer:

Department Chair:

Occupational Physician (as appropriate):

Veterinary Physician (as appropriate):

**Modification/Contingency:**

* + 1. IACUC approval required
			1. Completed CITI Training:
		2. IRB approval required
			1. IRB pending
			2. IRB approved
			3. IRB Number:

 iii IBC training required through CITI (Please click on [Instructions for Accessing CITI Training Modules](https://www.skidmore.edu/ibc/InstructionsforAccessingtheCITITrainingModulesv2.pdf) or visit [https://www.skidmore.edu/ibc/training.php)](https://www.skidmore.edu/ibc/training.php):

***Biosafety Level 1 Biosafety Level 2***

Required Courses Required Courses

☐ Emergency Response ☐ Emergency Response

☐ Biosafety Course Overview ☐ Laboratory Acquired Infections

Supplemental Courses Supplemental Courses

☐ OSHA Bloodborne Pathogens Standard ☐ NIH Guidelines for Research Involving

☐ Hepatitis B Virus (HBV) Vaccination Recombinant or Synthetic Nucleic Acid Molecules

☐ Label and Engineering Controls ☐ OSHA Bloodborne Pathogens Standard

☐ Universal Precautions and Work Practices ☐ Hepatitis B Virus (HBV) Vaccination

☐ Dual Use Research of Concern (DURC) ☐ Label and Engineering Controls

☐ Work Safety with Sharp Instruments ☐ Universal Precautions and Work Practices

☐ Centrifuge Precautions ☐ Dual Use Research of Concern (DURC)

☐ Shipping Regulated Biological Materials: Overview ☐ Work Safety with Sharp Instruments

 ☐ Centrifuge Precautions

 ☐ Shipping Regulated Biological Materials: Overview

 ☐ Animal Biosafety

***July 2021***