

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 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%2 Fpublications%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.

А	В	C	D	Е
If your experiment involves:	Registration	Registration	IBC must	Experiment
	w/ NIH	w/ IBC	receive	described on
	required?	required?	registration:	this form
	-	-	_	involves:
Cloning of DNA encoding toxin molecules lethal	Yes	Yes	Prior to	
to vertebrates at an LD ₅₀ of less than 100ng/kg			initiation	
Human gene therapy	Yes	Yes	Prior to	
			initiation	
Transfer of drug resistance to an organism not	Yes	Yes	Prior to	
known to naturally acquire that trait, if such an			initiation	
acquisition could compromise ability to control				
the disease in humans, veterinary medicine, or				
agriculture				
RG 2, 3, or 4 agents as host-vector systems	No	Yes	Prior to	
			initiation	
Cloning of DNA from RG 2, 3, or 4	No	Yes	Prior to	
microorganisms into nonpathogenic prokaryotic			initiation	
or lower eukaryotic host-vector systems				
Use of infectious DNA or RNA viruses or	No	Yes	Prior to	
defective DNA or RNA viruses in the presence of			initiation	
helper virus in tissue culture systems				
Use of transgenic animals at RG-2 or above	No	Yes	Prior to	
			initiation	
Use of viable rDNA modified microorganisms	No	Yes	Prior to	
involving whole animals or whole plants			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	No	Yes	At initiation	
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	Ŋ	37	A . • •.• .•	
Propagation and maintenance in tissue culture of	No	Yes	At initiation	
rDNA containing a virus that has been shown to				
be non-replicating	N	X7	A	
Formation of rDNA containing no more than 2/3	NO	Yes	At initiation	
of the genome of any eukaryotic virus	N	NT	/	
Use of transgenic animals at RG-1	NO	NO	n/a	
rDNA not in an organism or virus	NO	NO	n/a	
DINA segments from a single non-chromosomal	NO	INO	n/a	
or viral DNA source	N.	N.		
DINA entirely from a prokaryotic host when	INO	INO	n/a	
propagated only in that nost				

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

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):
 - a. Will the inserted gene(s) be expressed?
 - b. 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 (<u>http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=gene</u>)

- 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 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) 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:_____
- 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
- 2. What species will be exposed?
- 3. State the Institutional Animal Care and Use Committee active or pending

IACUC Protocol number:

- 4. State the maximum volume and concentration to be administered per animal:
- 5. State the maximum volume and concentration to be administered per experiment:
- 11. State 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/io dine 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 (Check all that apply)

- a. Personnel have completed required safety training within the past year. \Box
- b. Personnel have attended basic laboratory safety training.
- c. All personnel who are potentially exposed to blood, body fluids, or human cell lines have received Hepatitis B vaccine or have proven immunity.
- 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 Saratoga Hospital or Skidmore College Student Health Services for counseling.

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

g. 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 Training Date:
Signature:	Lab Safety Training Date:
Name:	CITI Training Date:
Signature:	Lab Safety Training Date:
Name:	CITI Training Date:
Signature:	Lab Safety Training Date:
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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:		
Signatures:		
IBC Chairman:		
Biological Safety Officer:		
Department Chair:		
Occupational Physician (as appr	ropriate):	
Veterinary Physician (as approp	priate):	

Modification/Contingency:

- i. IACUC approval required
 - 1. Completed CITI Training:
- ii. IRB approval required
 - 1. IRB pending
 - 2. IRB approved
 - 3. IRB Number:

iii IBC training required through CITI (Please click on <u>Instructions for Accessing</u> <u>CITI Training Modules</u> or visit <u>https://www.skidmore.edu/ibc/training.php</u>):

Biosafety Level 1*	Biosafety Level 2*
Required Courses	Required Courses
Emergency Response Biosafety Overview	Biosafety Course Overview Level 2
Supplemental Courses	Supplemental Courses
□ OSHA Bloodborne Pathogens Standard	□ NIH Guidelines for Research Involving
	Recombinant or Synthetic Nucleic Acid Molecules
	OSHA Bloodborne Pathogens Standard
□ Universal Precautions and Work Practices	\Box Work Safety with Sharp Instruments
	Universal Precautions and Work Practices
□ Shipping Regulated Biological Materials: Overview	Work Safety with Sharp Instruments
	□ Centrifuge Precautions
	□ Shipping Regulated Biological Materials: Overview
	Animal Biosafety

*A passing grade of 80 is required for EACH module completed, not a passing average of 80.

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