BATES COLLEGE
Institutional Biosafety Committee

Application for Research Involving Biological Materials and Recombinant DNA

INSTRUCTIONS:

All submissions must be typed. E-mail completed applications to **biosafety@bates.edu**. For questions or additional information, please e-mail **biosafety@bates.edu**. Please keep a copy of this application for your records.

SECTION I: GENERAL PROJECT INFORMATION

Application Status: ◉ New ○ Renewal (Annual), previous IBC#

○ Amendment, previous IBC#

If applicable, please indicate reason(s) for amendment (e.g., Contact Information, Summary of Project, Research Description, Personnel Changes, Occupational Health Issues, Location, NIH Guidelines, rDNA Construct, Infectious Materials, Other):

Principal Investigator's Name: Degree:

Department: Please select one Position: Please select one

Campus Address:

Office Phone: Lab Phone:

Emergency Phone: FAX:

E-mail Address:

Co-Principal Investigator's Name: Degree:

Department: Please select one Position: Please select one

Campus Address:

Office Phone: Lab Phone:

Emergency Phone: FAX:

E-mail Address:

Alternate Contact Name: (e.g. research assistant, lab technician, etc.)

E-mail Address for Alternate Lab Contact:

Office or Lab Phone: FAX:

SECTION II: GENERAL SUMMARY OF PROJECT

Materials to be used in this project (e.g., Recombinant DNA, gene transfer, host vector systems). Please list all:

Will you be using infectious agents (e.g., Bacteria, Virus, Yeast, Fungus, Prions, Parasitic agents)? If yes, please describe and identify the Risk Group of the agents (see Appendix B).

Note:

Risk Group 1 agents are exempt from IBC review. If there is no recombinant DNA research, an application is not needed. Please contact biosafety@bates.edu to request an official exemption letter.

Risk Group 2 agents must be approved by the IBC prior to the acquisition of agents.

Risk Group 3 agents are prohibited on the Bates campus.

Please answer the following:

Use of Human Subjects	○ Yes	◉ No
Use of Human/Nonhuman Primate Material (including all fluids, tissues, excretions, secretions, or cell lines)	○ Yes	◉ No
Use of transgenic or other genetically modified whole plants	○ Yes	◉ No
Use of transgenic or other genetically modified whole animals	○ Yes	◉ No
Use of animal specimens known to be reservoirs/vectors of Zoonotic diseases	○ Yes	◉ No

Use of biological toxins ○ Yes ◉ No

Use of CDC Select Agent (See appendix D for list) ○ Yes ◉ No

Will this work be part of a course (other than thesis or independent study)? ○ Yes ◉ No

Other (please specify)?

SECTION III: ANCILLARY APPROVALS

Committee	Yes	No	NA	Pending (date submitted)	Protocol Number	Most Recent Approval Date
IRB for use of human subjects	☐	☐	☐			
IACUC	☐	☐	☐			
Radiation Safety Officer	☐	☐	☐			
EHS	☐	☐	☐			
Other (specify)						

SECTION IV: RESEARCH DESCRIPTION

The IBC is made up of a diverse group of members. It is important to provide a description of the proposed research in language which is useful for scientific evaluation but general enough to be understood by members with non-science backgrounds. Please provide sufficient information to allow evaluation of the work for the purpose of accurate determination of biohazard risks (grant applications or abstracts are not acceptable).

List <u>all</u> program titles:

Identify the source(s) of funding to be used to support the research:

Provide a brief non-technical description and objectives of the research project. If this is a renewal provide updated information.

Describe in detail the procedures and techniques to be used in the research project or academic laboratory activities. If applicable, incorporate a description of any animal work (in vivo and/or ex vivo), human subjects, use of radiological materials, or other associated hazards in this project. Include mechanism for monitoring human or environmental exposure to pathogens or rDNA products and treatments or methods for mitigating risks to human or environmental health. (These will be part of the SOP.)

Describe in detail the rDNA used and generated in the research project. Describe the sources of the DNA, any antibiotic resistance markers and what the recombinant DNA will express and/or how it will be used.

SECTION V: PERSONNEL

In addition to taking the required safety training through CITI, each person working on the project is required to receive **formal (agent specific) training in the handling of biohazardous materials** prior to the beginning of the project from the PI or lab supervisor. Provide proof of formal training for each person listed. Contact **biosafety@bates.edu** if you have questions.

1. Principal Investigator's Experience – Describe qualifications and training of the PI and/or co-PI(s) pertaining to the biohazard and procedures in this project. Include a copy of current CV or bio sketch.

2. List all names of other personnel (Assistants in Instruction, Teaching Assistants, Research Technicians, Student Researchers, etc.) and indicate the responsibilities for each individual (see list below of responsibilities as follows):

Types of Responsibilities:	Directly handle biohazard material including bio waste
	User of equipment where biohazards are present
	Directly handle animals exposed to biohazard material
	Shipping biohazard material
	Handling hazardous chemicals with biohazard(s)
	Other (please specify)

SECTION VI: OCCUPATIONAL HEALTH IMMUNIZATIONS

In accordance with NIH Guidelines and CDC Biosafety in Microbiological and Biomedical Laboratories (5th Ed.):

- All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.
- Laboratory personnel must be provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the laboratory.

1. Prospective workers/current workers/students must be educated about the biohazard(s) listed in this protocol. Please mark if these items are/will be implemented in the laboratory.

All personnel must take CITI training prior to start of experiments ◉ Yes ○ No

All personnel must read the biosafety manual (with applicable agent specific hazard information) and adhere to the standard operating procedure related to this protocol. ◉ Yes ○ No

All personnel must receive laboratory orientation from the PI or Lab supervisor prior to the start of experiments to be knowledge-Able with, but not limited to the following: entry/exit procedure, Contact information in case of emergency, and location of safety Equipment (e.g. eye wash, shower, fire extinguisher, spill kit, etc.)

(●) Yes ( ) No

All personnel must demonstrate proficiency in standard and special microbiological practices before start of experiments.

(●) Yes ( ) No

Other Educational Training (Specify):

(●) Yes ( ) No

2. Describe any medical surveillance required for personnel more vulnerable to infection with the agents listed for this protocol. (e.g. non-vaccinated individuals, immune-deficient workers or non-immune pregnant female workers).

3. List applicable health surveillance/immunization programs to be recommended or implemented for this protocol. The IBC, upon review may change any of these items based on currently available federal, state and local Occupational Health recommendations.

4. In case of an exposure incident, describe the procedure that will be implemented for personnel to obtain consultation and treatment. Note: Students shall go to the Bates Health Center during regular business hours. For after hours, weekends or holidays, go to the CMMC Emergency Room.

SECTION VII: LOCATIONS OF STUDY

List building(s) and room number(s) where the following types of experiments will be performed:

Cell Culture Experiments -

Infected Animal Experiments -

Whole Plant Experiments -

SECTION VIII: NIH GUIDELINES ASSESSMENT FOR RESEARCH INVOLVING RECOMBINANT DNA (rDNA)

Please answer the following:

VIII A. Must be approved by the IBC, Recombinant DNA Advisory Committee and NIH Director before initiation of experiments. ◉ Yes ○ No

Definition: The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture. (Note that antibiotic resistance markers used for selecting and propagating plasmids in E. coli are not included.)

VIII B. Must be approved by NIH/OBA and IBC before initiation of experiments. ◉ Yes ○ No

Definition: Experiments involving the cloning of toxin molecules with LD50 of <100mg per kg body weight (e.g. microbial toxins such as botulinum toxin, tetanus toxin).

VIII C. Must be approved by IBC, IRB, and RAC review before research participant enrollment. ◉ **Yes** ○ **No**

Definition: Experiments involving the deliberate transfer of rDNA, or DNA or RNA derived from rDNA, into one or more human research participants.

NOTE: Attach response to Points to Consider: Appendix M of NIH Guidelines and submit any supplemental documents such as investigator brochure, clinical study, correspondence with NIH, etc.

VIII D. Must be approved by IBC before initiation of experiments ◉ **Yes** ○ **No**

NOTE: Introduction of rDNA into Risk Group 3 agents is not permitted at Bates.

Introduction of rDNA into Risk Group 2 (RG-2) agents ◉ Yes ○ No

Experiments in which DNA from RG-2 is transferred into nonpathogenic prokaryotes or lower eukaryotes. ◉ Yes ○ No

Use of infectious or defective RG-2 viruses in the presence of Helper virus. ◉ Yes ○ No

Use of infectious or defective restricted poxviruses in the presence of helper virus shall be determined on a case-by-case basis following NIH/OBA review. A USDA permit is required for work with plant or animal pathogens. ◉ Yes ○ No

Use of infectious or defective viruses in the presence of Helper virus not covered by the above categories. ◉ Yes ○ No

rDNA Involving Whole Animal

VIID-4-a. rDNA, or DNA or RNA molecules derived therefrom, from any source except for greater than two-thirds of eukaryotic viral genome may be transferred to any non-human vertebrate or any invertebrate organism and propagated under conditions of physical containment comparable to BSL-1 or BSL-1 N and appropriate to the organism under study. Animals that contain sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly as a result of complementation or recombination in animals, may be propagated under conditions of physical containment comparable to BSL-1 or BSL-1 N and appropriate to the organism under study. ◉ **Yes** ○ **No**

VIIID-4-b. Experiments involving rDNA or DNA or RNA derived therefrom, involving whole animals, including transgenic animals ◯Yes ◯No

VIIID-4-c-1. Experiments involving the generation of transgenic rodents that require BSL1 containment. ◯Yes ◯No

VIIID-4-c-2. Purchase or transfer of transgenic rodents is exempt from the "NIH Guidelines", but register with the IBC. ◯Yes ◯No

rDNA Involving Whole Plants: For rDNA experiments falling under Sections III-D-5-a through III-D-5-d, physical containment requirements may be reduced to the next lower level by appropriate biological containment practices, such as conducting experiments on a virus with an obligate insect vector in the absence of that vector or using a genetically attenuated strain.

VIIID-5-a. BSL3-P (Plants) or BSL2-P + biological containment is recommended for experiments of most exotic infectious agents with recognized potential for serious detrimental impact on managed or natural ecosystems when rDNA techniques are associated with whole plants. ◯Yes ◯No

VIIID-5-b. BSL3-P or BSL2-P + biological containment is recommended for experiments involving plants containing cloned genomes of readily transmissible exotic infectious agents with recognized potential for serious detrimental effects on managed or natural ecosystems in which there exists the possibility of reconstituting the complete and functional genome of the infectious agent by genomic complementation *in planta.* ◯Yes ◯No

VIIID-5-c. BSL4-P containment is recommended for experiments with a small number of readily transmissible exotic infectious agents, such as the soybean rust fungus (Phakospora pachyrhizi) and maize streak or other viruses in the presence of their specific arthropod vectors that have the potential of being serious pathogens of major U.S. crops. ◯Yes ◯No

VIIID-5-d. BSL3-P containment is recommended for experiments involving sequences encoding potent vertebrate toxins introduced into plants or associated organisms (also refer to Section III-B-1). ◯Yes ◯No

VIIID-5-e. BSL3-P or BSL2-P + biological containment is recommended for experiments with microbial pathogens of insects or small animals associated with plants if the rDNA-modified organism has a recognized potential for serious detrimental impact on managed or natural ecosystems. ◯Yes ◯No

VIIID-6. Experiments involving more than 10 liters of culture. The appropriate containment will be decided by the IBC. ◯Yes ◯No

VIII E. Must notify IBC simultaneously upon initiation of research.

VIIIE1. Experiments involving the formation of rDNA molecules containing no more than 2/3 of the genome of any eukaryotic virus (All viruses from a single Family being considered identical.) may be propagated and maintained in cells in tissue culture using BSL1. ◯Yes ◯No

VIIIE2-a. BSL1-P is recommended for all experiments with rDNA-containing plants and plant-associated microorganisms not covered in Section III-E-2-b or other sections of the NIH Guidelines. Examples of such experiments are those involving rDNA-modified plants that are not noxious weeds or that cannot interbreed with noxious weeds in the immediate geographic area, and experiments involving whole plants and rDNA-modified non-exotic microorganisms that have no recognized potential for rapid and widespread dissemination or for serious detrimental impact on managed or natural ecosystems (e.g., *Rhizobium* spp. and *Agrobacterium* spp.). ◯Yes ◯No

VIIIE-2-b. BSL2-P or BSL1-P + biological containment is recommended for the following experiments:

VIIIE2-b-(1). Plants modified by rDNA that are noxious weeds or can interbreed with noxious weeds in the immediate geographic area. ◯Yes ◯No

VIII-E-2-b-(2). Plants in which the introduced DNA represents the complete genome of a non-exotic infectious agent. ◯Yes ◯No

VIII-E-2-b-(3). Plants associated with rDNA-modified non-exotic microorganisms that have a recognized potential for serious detrimental impact on managed or natural ecosystems. ◯Yes ◯No

VIII-E-2-b-(4). Plants associated with rDNA-modified exotic microorganisms that have no recognized potential for serious detrimental impact on managed or natural ecosystems. ◯Yes ◯No

VIII-E-2-b-(5). Experiments with rDNA-modified arthropods or small animals associated with plants, or with arthropods or small animals with rDNA-modified microorganisms associated with them if the rDNA-modified microorganisms have no recognized potential for serious detrimental impact on managed or natural ecosystems. ◯Yes ◯No

VIIIE-3. Experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of rDNA, or DNA derived therefrom, into the germ0line (transgenic rodents). ◯Yes ◯No