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 jsmith7@bates.edu Submit one original application with all original signatures and complete applicable attachments to: Jessica Smith, Director of Environmental Health and Safety, 215 College Street, Lewiston, ME 04240. For questions or additional information call 786-8226 or e-mail jsmith7@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, IBC#_____ Note: 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

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Principal Investigator's Name:_____ Degree:_____

Department:_____ Position: Faculty (if other specify) _____

Campus Address:_____

Office Phone:_____ Lab Phone:_____Emergency Phone:_____

FAX:_____

E-mail:_____

Co-Principal Investigator's Name:_____ Degree:_____

Department:_____ Position: Faculty (if other specify) _____

Campus Address:_____

Office Phone:_____ Lab Phone:_____ Emergency Phone:_____

FAX:_____

E-mail:_____

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

E-mail Alternate Lab Contact: _____

Office or lab Phone:_____ FAX: _____

SECTION II: GENERAL SUMMARY OF PROJECT

Materials to be used in this project: Please list all.

Example: Recombinant DNA, gene transfer, host vector systems

Will you be using infectious agents? (Bacteria, Virus, Yeast, Fungus, Prions, Parasitic agents)
Describe:

If yes, identify the Risk Group of the agents (see Appendix B).

Note: Risk Group 3 agents are prohibited on the Bates campus.

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

Risk Group 1 agents are exempt from IBC review. If there is no recombinant DNA research an application is not needed. Contact jsmith7@bates.edu to request an official exemption letter.

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 (specify)?	Yes_____	No_____

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 all 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 jsmith7@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 other personnel (Assistants in Instruction, Teaching Assistants, Research Technicians, Student Researchers, etc.) and indicate the responsibilities for each individual as follows:**

Name:_____ Position Title:_____

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 (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.

All personnel must take CITI training prior to start of experiments **Y** **N**

All personnel must read the biosafety manual (with applicable agent specific hazard information) and adhere to the standard operating procedure related to this protocol.	**Y**	**N**
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.)	**Y**	**N**
All personnel must demonstrate proficiency in standard and special microbiological practices before start of experiments.	**Y**	**N**
Other Educational Training (Specify):	**Y**	**N**

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.

Students shall go to the Bates Health Center during regular business hours. For after hours, weekends or holidays, go to the CMMC Emergency Room.

Other (Specify)

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)

Mark the sections that apply

VIII A Must be approved by the IBC, Recombinant DNA Advisory Committee and NIH Director before initiation of experiments. **Y** **N**

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. **Y N**

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. **Y N**

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 **Y N**

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

Introduction of rDNA into Risk Group 2 (RG-2) agents **Y N**

Experiments in which DNA from RG-2 is transferred into nonpathogenic prokaryotes or lower eukaryotes. **Y N**

Use of infectious or defective RG-2 viruses in the presence of Helper virus. **Y N**

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. **Y N**

Use of infectious or defective viruses in the presence of Helper virus not covered by the above categories. **Y N**

rDNA Involving Whole Animal

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. **Y N**

Experiments involving rDNA or DNA or RNA derived therefrom, involving whole animals, including transgenic animals, and not covered by