FORDHAM UNIVERSITY

Institutional Biosafety Committee

Recombinant DNA Protocol

As Principal Investigator:

☐ I attest that the information in the registration is accurate and complete, and I will submit significant changes to the Institutional Biosafety Committee before implementation.

☐ I am familiar with, and agree to abide by, the current applicable guidelines and regulations governing my research, including, but not limited to, the NIH *Guidelines for Research Involving Recombinant and Synthetic DNA Molecules* and *Biosafety in Microbiological and Biomedical Laboratories.*

☐ I have completed all required institutional training and I agree to accept responsibility for ensuring all laboratory personnel involved in this research have the required and necessary training on potential biohazards, relevant biosafety practices, techniques, and emergency procedures.

☐ If applicable, I have carefully reviewed the NIH Guidelines and accept the responsibilities described therein for principal investigators (Section IV-B-7).

☐ I will notify the Campus Safety department, the Institutional Biosafety Committee, and the Department of Environmental Health and Safety (EHS) concerning any research related accidents or exposure incidents.

☐ I agree that no work will be initiated prior to project approval by the Institutional Biosafety Committee.

Principal Investigator: Printed Name

PI Signature: **Date:**

Certification of Approval by the IBC

IBC Chair: **Date:_____**

Signature

Biosafety level assigned to project:_____

Date of Expiration (Certification must be renewed every 3 years.) _____

PI CONTACT INFORMATION

Department:_____

Lab Address:_____

Lab Telephone Number:_____ E-mail Address: _____

After hours phone number (required if research is at Biosafety Level 2):_____

1. DESCRIPTION OF RECOMBINANT DNA PROJECT

Project Title:

a. Concisely describe the overall nature of your work regarding recombinant DNA (e.g. construction of gene expression plasmids for transfection into mammalian cells, or retroviral vectors used to express transcription factors in rat brains… etc.)

b. List the host(s) that will be used, e.g., *E. coli*, mammalian cell line, mouse, humans, etc:

c. List and describe the vector(s) (plasmids, viral, etc.) that will be used and if the vector is replication defective, explain the molecular basis for this designation, e.g., adenovirus, E1 and E3 deleted; FIV, gag and pol deleted, etc. What volume of vector culture and stock will be produced at any one time?

Project Description:

Provide the section of the NIH Guidelines for Research Involving Recombinant DNA/RNA that covers your proposed project. III-D-3

Is this project exempt from these guidelines?

No ☐ **If no, continue filling out the remainder of this form.**

Yes ☐ **If yes, please sign the statement below. No need to fill out remainder of this form.**

I (Print name): _____ have read and understand my obligations under NIH Guidelines for Research Involving Recombinant DNA Molecules and certify to the University that this project is exempt.

Signature (PI): _____ Date: _____

NOTE: If research project has changes which alter the status to non-exempt, you must update and resubmit form.

The applicable sections of the NIH RDNA Guidelines are located at this URL: https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf

Exempt Experiments:

III-F-1	Recombinant DNA organisms that are not in organisms or viruses (e.g., amplification of DNA by PCR, nucleic probes, etc.)
III-F-2	R-DNA molecules consisting entirely of DNA from a single nonchromosomal or viral DNA source.
III-F-3	R-DNA molecules consisting entirely of DNA from a prokaryotic host including its indigence plasmids or viruses when propagated only in that host or transferred to another host by known physiological means.
III-F-4	R-DNA molecules consisting entirely of DNA from a eukaryotic host (including mitochondria, chloroplasts, or plasmids but excluding viruses) when propagated only in that host.
III-F-5	R-DNA molecules consisting entirely of DNA segments from different species that exchange DNA by known physiological processes.
III-F-6	**Experiments not posing significant risk to health or the environment. See Appendix C. This includes recombinant DNA molecules that are propagated using common non-pathogenic bacterial or yeast host-vector systems, e.g., E. coli K12, tissue or cell culture.**
III-F-7	Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA.
III-F-8	Those that do not present a significant risk to health or the environment (see Section IV-C-1-b-(1)-(c), *Major Actions*), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C, *Exemptions under Section III-F-8* for other classes of experiments which are exempt from the *NIH Guidelines*.

Non-Exempt Experiments:

III-A-1	The transfer of drug resistance trait to a microorganism if such transfer could compromise the use of drugs to control disease. [Note, unless there is a significant technical reason why an organism that's resistant to antibiotics that are currently used to treat disease states in humans and animals, must be used, the protocol will not be approved.]
III-B-1	Cloning of toxin molecules with LD50 less than 100 ng/Kg.
III-C-1	Transfer of recombinant nucleic acids in human research participants.
III-D-1	Use of Risk Group 2, 3 or 4 organisms as host-vector systems. Note: Refer to Appendix B for listings of organisms in the various Risk Groups: or contact ADD Biosafety if there are questions.
III-D-2	Cloning of Risk Group 2, 3 or 4 organisms into non-pathogenic prokaryotic or lower eukaryotic host-vector systems.
III-D-3	Use of infectious DNA/RNA viruses or defective viruses in the presence of helper viruses.
III-D-4	Stable introduction of recombinant DNA into an animal genome, or testing of recombinant DNA organisms in whole animals.
III-D-5 or III- E-2	Experiments with genetically altered plants.
III-D-6	Culture volumes of greater than 10 L in a given experiment
III-E-1	DNA molecules containing two thirds or more of any eukaryotic viral genome.
III-E-3	Experiments involving transgenic rodents

d. Are any of the recombinant vectors integration competent? Yes ☐ No ☐ N/A ☐

e. Are any of the recombinant transgenes oncogenic? Yes ☐ No ☐ N/A ☐

Note regarding viral vectors: expression of oncogenes may increase the associated risk and require extra precautions especially if these vectors are integration competent. If you are expressing highly oncogenic transgenes please describe them and any enhanced procedures or additional precautions below.

f. List any antibiotic resistance genes that will be engineered into any host below:

Will the proposed transfer of these genes to organisms be clinically relevant (i.e., will the antibiotic resistance genes confer resistance to antibiotics that are used to treat human or animal infections caused by the organisms into which the resistance genes will be transferred)?
Yes ☐ No ☐

If yes, NIH must approve this project prior to IBC review. Contact the IBC Chair.

g. Are any of your transgenes toxic (see below)? Yes ☐ No ☐

List all of the toxin(s):

Note regarding the insertion of rDNA that encodes toxin molecules: Experiments involving rDNA that encodes toxins with a LD50 of less than 100 nanograms/kg body weight must be approved by NIH/OBA prior to review by the IBC. Contact the IBC Chair.

h. Do any of the vectors in your laboratory contain more than 2/3 of the genome of a pathogen?
Yes ☐ No ☐

If yes please describe this pathogen:

i. Will your work involve the use of lentiviral vectors?

Yes ☐ No ☐

If yes:

1. How is the viral vector produced (e.g. 4-plasmid transfection system)?

2. Are the lentivirus vectors self-inactivating (SIN)?

j. Will this research involve transfer of rDNA into human subjects? Yes ☐ No ☐

Note regarding human subjects: Experiments involving the deliberate transfer of rDNA into one or more human subjects **must** be approved by the Recombinant DNA Advisory Committee at NIH (RAC) prior to submission and approval from the IBC and IRB. Contact the IBC Chair for more information.

k. Will this research involve transfer of rDNA/rRNA vectors into animals? Yes ☐ No ☐

If yes, specify what rDNA and/or recombinant organisms will be administered **and** the route of administration. **Note: projects involving vertebrate animals require IACUC approval.**

l. Using the table below, please indicate the highest biosafety level for your laboratory.

Biological Safety Level (BL)	BSL1	BSL2	BSL3*	BSL4*
Appropriate for organisms with the following characteristics:	Not known to consistently cause disease in healthy adults.	Associated with human disease, hazard = percutaneous injury, ingestion, mucous membrane exposure.	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences.	Dangerous/exotic agents which pose high risk of life-threatening disease, aerosol-transmitted lab infections, or related agents with unknown risk of transmission.

**** currently there are no facilities at Fordham University that can accommodate these biosafety levels.***

Please refer to "Biosafety in Microbiological and Biomedical Labs, 6th Ed." at the following URL: https://www.cdc.gov/labs/bmbl.html

Note: If any other laboratories at Fordham University will be using recombinant materials from your laboratory they must get approval from the IBC before commencing any related work with these recombinant agents.

2. AEROSOLS

a. Conducting procedures that can produce aerosols containing recombinant agents must be controlled using standard approved protocols, PPE, and engineering controls**.**

Is your laboratory following these practices? Yes ☐ No ☐ N/A ☐

b. If you are making modifications to these best practices please describe them below. Also explain why these modifications are necessary, and describe how you will compensate to maintain a safe working environment.

3. SHARPS

a. The use of sharps in conjunction with recombinant DNA can be dangerous and should be eliminated if at all possible (e.g. the use of glass pipettes with BSL2 agents should not be done), or safer engineered sharps devices should be used**.**

Is your laboratory in compliance with these practices? Yes ☐ No ☐ N/A ☐

b. If you are using sharps and are deviating from the best practices please describe these deviations, explain why they are necessary, and describe how you will compensate to maintain a safe working environment below.

4. WASTE DISPOSAL METHODS

a. Minimum standard requirements must be followed when disposing of liquid waste, stocks, disposable labware, and pathological waste contaminated with biological hazards**.**

Is your laboratory following these practices? Yes ☐ No ☐

b. Please describe any deviations or additions to the best practices:

If there are any other types of contaminated biohazardous waste generated in your laboratory please describe it and your method of disposal here:

5. FLOW CYTOMETRY AND FACS

a. Will you be conducting flow cytometry or fluorescence activated cell sorting (FACS).
Yes ☐ No ☐

If yes you must complete and append the Flow/Cell Sorter Biosafety Information form.

b. Is your laboratory following these practices? Yes ☐ No ☐

c. Please describe any deviations or additions to the best practices below:

6. OTHER INFORMATION

It is the responsibility of the principle investigator to assess the risks and ensure appropriate measures are in place to protect laboratory members and the general public. If there are any other significant potential hazards related to recombinant DNA that have not been sufficiently described above please do so in the space provided below. Discuss the nature of the hazard and protective measures put in place below.

7. TRANSPORTATION/SHIPMENT OF BIOLOGICAL MATERIALS

a. As per the Department of Transportation **49 CFR Parts 171-173** (7), some biological materials are regulated as hazardous materials and require special training of all personnel involved in shipping.

Will you be transporting or shipping any of the following off campus?
Yes ☐ No ☐

If yes, check all that apply

☐ Cultures of human or animal pathogens

☐ Environmental samples known or suspected to contain a human or animal pathogen

☐ Human or animal material (including excreta, secreta, blood and its components, tissue and tissue fluids, cell lines, and other biohazardous materials) containing or suspected of containing a human or animal pathogen.

☐ Have you or anyone in your lab involved in packaging, labeling, or completing/signing paper work received training to ship infectious substances or diagnostic specimens within the past 3 years?

Yes ☐ No ☐

If yes, please provide the following information:

Name	**Date Trained**	**Certified Shipping Trainer**

8. PERSONNEL QUALIFICATIONS & FACILITY INFORMATION

a. List qualifications of the PI and personnel with relevant training and experience with the recombinant DNA procedures described.

Name (first and last) – POSITION (Title, academic degrees, certifications, and field of expertise)	**RELEVANT EXPERIENCE** **(Describe previous work and training with biohazardous and/or recombinant DNA and include Biosafety Levels)**
Example: Bob Biohazard – Associate Professor, PhD- Microbiology	*14 yrs working with E. coli at BL1, Salmonella enterica at BL2, 8 yrs working with transgenic mice*

b. List all the laboratories/facilities where research is to be conducted (specify building, room number and category for each):

Building	**Room #**	**Category**	**Check if a new or updated biohazard door sign is needed***
			☐
			☐
			☐
			☐
			☐

***Biohazard signs are required for entrances to Biosafety Level 2 areas. The Department of Environmental Health and Safety will provide signs**.
If an updated biohazard sign is required, please indicate the location and what agents/organisms/hazards should be listed on the sign in addition to what is being registered.

REFERENCES

1. *Biosafety in Microbiological and Biomedical Laboratories:* BMBL – 6th ed. CDC – Dept. of Health and Human Services:

2. *NIH Guidelines for work involving recombinant DNA molecules.*

3. Department of Transportation – Hazardous Materials: Standards for Infectious Substances; **49 CFR Parts 171-173**