NYIT College of Osteopathic Medicine

Institutional Biosafety Committee
Biosafety Protocol Form
For Recombinant DNA and Microorganisms in Research

PRINCIPAL INVESTIGATOR:

Submission Date: **Title:**

1. Briefly describe research in terms that a layman can understand.

2. List all persons who will be involved in the project including students and animal care personnel.

Last Name	**First Name**	**Status** (PI, technician, student, etc.)	**Experience with rDNA involving infectious agent (years)**	**Experience with rDNA involving non-infectious agent (years)**

3. Who will train individuals with little or no experience and those switching from non-infectious to infectious agents?

4. Does project involve use of infectious materials? If "**no**," indicate "no" in space below. If "**yes**," describe in the space below.

5. Describe the host cells in which recombinant DNA will be introduced.

6. Describe the vector to be used? If a helper virus is also to be used, it must also be described. If not, indicate "no helper virus required" in the space below.

7. Identify the DNA to be inserted including the genes encoded within the DNA. Identify the source of the DNA (mammalian, non-mammalian eukaryotic, prokaryotic, viral, synthetic).

8. Is the inserted DNA or vector derived from a pathogen or potential pathogen? If "yes," describe below. If "no," indicate "no" below.

9. Does the inserted DNA or vector encode a toxin or potential toxin? If "yes," describe below, and indicate whether the toxin can injure humans, other vertebrates, invertebrates, or plants. Also, include the LD_{50} of the toxin in ng/kg. If "no," indicate "no" below.

10. List the volume of material that will be cultured (liters).

11. Identify the risk group that encompasses your project.

- ☐ Risk Group 1- agents that are not normally associated with disease in healthy adult humans.
- ☐ Risk Group 2 – agents that are associated with human diseases which are rarely serious and for which preventive or therapeutic intervention are often available.
- ☐ Risk Group 3 – agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available (high individual risk but low community risk).

12. Identify equipment to be used in the project.

- Biosafety cabinet
- Ultracentrifuge

- Other equipment (name and location).

13. Describe decontamination procedures for equipment in #11.

14. Describe decontamination procedures for the lab in which the research will be done.

15. Identify location(s) where biohazard and other warning signs will be posted.

16. All waste containing recombinant DNA or recombinant DNA modified organisms must be processed as regulated medical waste, and disposed of accordingly.

    Confirm by checking box ☐

17. Describe how other hazardous wastes will be processed and stored in the lab prior to pickup for disposal.

18. List all hazardous chemicals and controlled substances to be used in the project. You may be asked to provide material data safety sheets (MSDS) for the chemicals and to consult with Environmental Health and Safety prior to the start of the research.

19. If the proposed research involves the use of vertebrate animals, provide the protocol number and approval date from your animal use application to the Institutional Animal Care and Use Committee. If yes, answer questions #18 and #19. If vertebrate animals are not to be used, indicate “no vertebrate animal use.”

20. Does the project involve whole vertebrate animals in which the animal's genome has been altered by stable introduction of recombinant DNA or DNA derived from it into the germ-line (transgenic animals)?

No ☐

Yes ☐

21. Does the research involve viable recombinant DNA modified microorganisms or viruses tested on whole vertebrate animals?

No ☐

Yes ☐

Responsibilities of Principal Investigator

1. The principal investigator's electronic signature on this proposal to the Institutional Biosafety Committee certifies:

   a. That the research described herein will be conducted in full compliance with all federal, state and local policies regulating recombinant DNA research including NIH guidelines at http://oba.od.nih.gov/rdna/nih_guidelines_oba.html. **A list of appropriate guidelines should be listed at the end of the protocol by the principal investigator**.

   b. That the principal investigator agrees to adhere to the guidelines in the New York Institute Technology Biosafety Manual.

   c. That the principal investigator is full cognizant of the details of the proposal and will conduct all aspects of the project as approved by the Institutional Biosafety Committee.

   d. That principal investigator will request the Institutional Biosafety Committee's approval before making any changes to the procedures in this approved protocol.

   e. That principal investigator will request the Institutional Biosafety Committee's approval before making any additions to personnel working on the project, and will notify the Committee of any deletions in personnel.

   f. That the principal investigator will ensure that the principal investigator and any person involved in any aspect of the project will not perform procedures for which the person has not been trained and/or certified or licensed (where required).

   g. That the principal investigator is aware of potential hazards, safe work practices, and necessary training as related to this project.

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2. **Principal Investigator's electronic signature**.

Action of Institutional Biosafety Committee

1. Containment level determined by the Institutional Biosafety Committee:

2. Reviewed and returned to principal investigator with comments for revision.

3. Approved

   a. Approved by vote of:

   b. Approval Date:

   c. Signature of IBC Chairman:

Principal investigator must list the guidelines to be followed by those engaged in the project in the space below.