

SUNY NEW PALTZ
Policy Statement

RESEARCH INVOLVING RECOMBINANT DNA MOLECULES

SUNY New Paltz is committed to the safe conduct of experiments involving recombinant DNA and to the protection of health and of the environment. In consideration of these commitments and of the SUNY New Paltz facilities available for such research, the following safeguards are implemented. SUNY New Paltz (and the Institutional Biosafety Committee acting on its behalf) takes the responsibility for ensuring that recombinant DNA activities comply with the intent as well as the specifics of the National Institutes of Health "Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), June 1994" and amendments to the guidelines "Recombinant DNA Research: Actions Under the Guidelines," Federal Register, Vol. 61, No. 13 Friday, January 19, 1996.

Applicability

This policy applies to funded and non-funded, experimental or instructional projects involving recombinant DNA Molecules conducted by students, faculty, staff or affiliate researchers on campus or off campus. The policy covers ALL activities involving recombinant DNA conducted under the auspices of the College, used or to be used in any professional activity or publication in which the individual claims an affiliation with SUNY New Paltz, used or to be used in support of retention, promotion, tenure and/or merit decisions and includes research classified as individual or institutional.

Allowable Activities

Allowable research and other experimental or instructional activities are limited to those which may be conducted within containment levels no higher than BL1. (Refer to Section III, NIH Guidelines, pp. 6-10 and Appendix C (pp. 24-27). No recombinant DNA experiments are to be conducted with human subjects.

No experiments necessitating a health surveillance program are to be conducted. No regulated DNA experiments are to be conducted utilizing plants. No recombinant DNA experiments are to be conducted utilizing animals without review and approval by the Institutional Animal Care and Use Committee.

Participation as a consultant in sponsored research conducted by another institution at its site may be exempt upon demonstration of appropriate review by that institution.

Definitions

Recombinant DNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed in vivo as a biologically active polynucleotide or polypeptide product, it is exempt from the guidelines.

Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the guidelines unless the transposon itself contains recombinant DNA.

Biosafety Level 1

Biosafety Level 1 is suitable for work involving agents of no known or minimal potential hazard to laboratory personnel and the environment. The laboratory is not separated from the general traffic patterns in the building. Work is generally conducted on open bench tops. Special containment equipment is not required or generally used. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training in microbiology or a related science. Refer to Attachment 2.

Roles and Responsibilities

Responsibilities of the Institution

Each institution conducting or sponsoring recombinant DNA research which is covered by the NIH Guidelines is responsible for ensuring that the research is conducted in full conformity with the provisions of the NIH Guidelines. In order to fulfill this responsibility, the institution shall:

Establish and implement policies that provide for the safe conduct of recombinant DNA research and that ensure compliance with the NIH Guidelines. As part of its general responsibilities for implementing the NIH Guidelines, the institution may establish additional procedures, as deemed necessary, to govern the institution and its components in the discharge of its responsibilities under the NIH Guidelines. Such procedures may include (i) statements formulated by the institution for the general implementation of the NIH Guidelines, and (ii) any additional precautionary steps the institution deems appropriate.

Establish an Institutional Biosafety Committee that meets the requirements and carries out the functions detailed in the NIH Guidelines.

Assist and ensure compliance with the NIH Guidelines by Principal Investigators conducting research at the institution as specified in Section IV-B-4 of the NIH Guidelines.

Ensure appropriate training for the Institutional Biosafety Committee Chair and members, Biological Safety Officer (when applicable), Principal Investigators, and laboratory staff regarding laboratory safety and implementation of the NIH guidelines. The Institutional Biosafety Committee Chair is responsible for ensuring that Institutional Biosafety Committee members are appropriately trained. The Principal Investigator is responsible for ensuring that laboratory staff is appropriately trained. The institution is responsible for ensuring that the Principal Investigator has sufficient training. Report any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to NIH/ORDA within thirty days. Reports shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Suite 323, 6006 Executive Boulevard, MSC 7052, Bethesda, Maryland 20892-7052, (301) 496-9838.

Institutional Biosafety Committee (IBC)

The institution shall establish an Institutional Biosafety Committee whose responsibilities need not be restricted to recombinant DNA. The Institutional Biosafety Committee shall meet the following requirements:

Membership and Procedures

The Institutional Biosafety Committee must be comprised of no fewer than five members so selected that they collectively have experience and expertise in recombinant DNA technology and the capability to assess the safety of recombinant DNA research and to identify any potential risk to public health or the environment. At least two members shall not be affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and who represent the interest of the surrounding community with respect to health and protection of the environment (e.g., officials of state or local public health or environmental protection agencies, members of other local governmental bodies, or persons active in medical, occupational health, or environmental concerns in the community). Of those members affiliated with the institution, one shall be the Environmental Health and Safety Coordinator. This individual will serve as the Biological Safety Officer on the IBC. The Institutional Biosafety Committee shall include at least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P (of the NIH Guidelines) require prior approval by the Institutional Biosafety Committee. The Institutional Biosafety Committee shall include at least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q of the NIH Guidelines require Institutional Biosafety Committee prior approval.

In order to ensure the competence necessary to review and approve recombinant DNA activities, it is recommended that the Institutional Biosafety Committee: (1) include persons with expertise in recombinant DNA technology, biological safety, and physical containment; (2) include or have available as consultants persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment, and (3) include at least one member representing the laboratory technical staff.

The institution shall file a report with NIH/ORDA which includes the names and biographical sketches of all Institutional Biosafety Committee members, including community members, in such form and at such times as required by NIH/ORDA.

No member of an Institutional Biosafety Committee may be involved (except to provide information requested by the Institutional Biosafety Committee) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest. When the chair of the IBC is the principal investigator of a proposal involving recombinant DNA, the chair will appoint and acting chair for the review of that proposal. The institution, which is ultimately responsible for the effectiveness of the Institutional Biosafety Committee, may establish procedures that the Institutional Biosafety Committee shall follow in its initial and continuing review and approval of applications, proposals, and activities.

When possible and consistent with protection of privacy and proprietary interests, the institution is encouraged to open its Institutional Biosafety Committee meetings to the public.

Upon request, and consistent with institutional procedures, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public. If public comments are made on Institutional Biosafety Committee actions, the institution shall forward both the public comments and the Institutional Biosafety Committee's response to the Office of Recombinant DNA Activities, National Institutes of Health, Suite 323, 6006, Executive Boulevard, MSC 7052, Bethesda, Maryland 20892 – 7052, (301) 496-9838.

Functions

On behalf of the institution, the Institutional Biosafety Committee is responsible for:

Reviewing recombinant DNA research conducted at or sponsored by the institution for compliance with the NIH Guidelines as specified in Section III and approving those research projects that are found to conform with the NIH Guidelines. This review shall include: (1) independent assessment of the containment levels required by the NIH Guidelines for the proposed research, and (2) assessment of the facilities, procedures, practices and training and expertise of personnel involved in recombinant DNA research. Refer to Attachment 1, "Institutional Biosafety Committee Criteria for Evaluating Recombinant DNA Experiments."

Notifying the Principal Investigator of the results of the Institutional Biosafety Committee's review and approval.

Lowering containment levels for certain experiments as specified in Section III – C-2-a of the NIH Guidelines.

Setting containment levels as specified in Sections III – C-4-b and III – C-5 of the NIH Guidelines.

Annual reviewing of recombinant DNA research and instructional activities conducted at the institution to ensure compliance with the NIH Guidelines. Adopting emergency plans covering accidental spills and personnel contamination resulting from recombinant DNA research.

Note: The Laboratory Safety Monograph describes basic elements for developing specific procedures dealing with major spills of potentially hazardous materials in the laboratory, including information and references about decontamination and emergency plans. The NIH and the Centers for Disease Control and Prevention are available to provide consultation and direct assistance, if necessary, as posted in the Laboratory Safety Monograph. The institution shall cooperate with the state and local public health departments by reporting any significant research-related illness or accident that may be hazardous to the public health.

The Chair of the Institutional Biosafety Committee is responsible for reporting any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the Biological Safety Officer and to the Provost/Vice President for Academic Affairs with whom reporting to NIH/ORDA will be coordinated to meet the 30 day reporting requirement. Reports to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Suite 323, 6006 Executive Boulevard, MSC 7052, Bethesda, Maryland 20892-7052, (301) 496-9838.

The Institutional Biosafety Committee may not authorize initiation of experiments which are not explicitly covered by the NIH Guidelines until NIH (with the advice of the RAC when required) establishes the containment requirement.

Performing such other functions as may be delegated to the Institutional Biosafety Committee under Section IV-B-2 of the NIH Guidelines.

Biological Safety Officer (BSO)

The institution shall appoint a Biological Safety Officer, who will serve as a member of the Institutional Biosafety Committee.

The Biological Safety Officer's duties include, but are not limited to:

Periodic inspections to ensure that laboratory standards are rigorously followed;

Reporting to the Institutional Biosafety Committee and the Provost/Vice President for Academic Affairs any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses of which the Biological Safety Officer becomes aware unless the Biological Safety Officer determines that a report has already been filed by the Principal Investigator.

Ensuring emergency plans are in place for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant DNA research;

Providing advice on laboratory security;

Providing technical advice to Principal Investigators and the Institutional Biosafety Committee on research safety procedures.

Note: See Laboratory Safety Monograph for additional information on the duties of the Biological Safety Officer.

Principal Investigator

On behalf of the institution, the Principal Investigator is responsible for full compliance with the NIH Guidelines in the conduct of recombinant DNA research.

General Responsibilities

As part of this general responsibility, the Principal Investigator shall:

Initiate or modify no recombinant DNA research which requires Institutional Biosafety Committee approval prior to initiation (see Sections III-A, III-B, and III-C of the NIH Guidelines) until that research or the proposed modification thereof has been approved by the Institutional Biosafety Committee and has met all other requirements of the NIH Guidelines;

Recommends to the IBC whether experiments are covered by Section III-D of the NIH Guidelines and that the appropriate procedures are followed;

Report any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to the Biological Safety Officer (where applicable), Greenhouse/Animal Facility Director (where applicable), Institutional Biosafety Committee, NIH/ORDA and other appropriate authorities (if applicable) within 30 days (reports to NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Suite 323, 6006 Executive Boulevard, MSC 7052, Bethesda, Maryland 20892-7052, (301) 496-9838. **The Institutional Biosafety Committee Chair must be notified immediately. The Chair will immediately notify the Biological Safety Officer and the Provost/Vice President for Academic Affairs with whom reporting to the NIH/ORDA will be coordinated to meet the 30 day reporting requirement. Documentation of notification must be provided by the VPAA to the Principal Investigator no later than 27 days after the incident.**

Report any new information bearing on the NIH Guidelines to the Institutional Biosafety Committee and to NIH/ORDA (reporting procedure same as that in bold above).

Be adequately trained in good microbiological techniques;

Adhere to Institutional Biosafety Committee-approved emergency plans for handling accidental spills and personnel contamination; and

Comply with shipping requirements for recombinant DNA molecules (see Appendix H of the NIH Guidelines for shipping requirements and the Laboratory Safety Monograph for technical recommendations).

Submissions by the Principal Investigator to the NIH/ORDA

The Principal Investigator shall:

Submit information to NIH/ORDA for certification of new host-vector systems;

Petition NIH/ORDA, with notice to the Institutional Biosafety Committee, for proposed exemptions to the NIH Guidelines.

The Principal Investigator is responsible for other requirements as specified in the NIH Guidelines.

Submissions by the Principal Investigator to the Institutional Biosafety Committee

The Principal Investigator shall:

Make an initial determination of the required levels of physical and biological containment in accordance with the NIH Guidelines;

Select appropriate microbiological practices and laboratory techniques to be used for the research; Submit the initial research protocol and any subsequent changes (e.g., changes in the source of DNA or host-vector system) utilizing the Institutional Biosafety Committee Notification Form (refer to Attachment 3) to the Institutional Biosafety Committee for review and approval or disapproval one month prior to proposal submission or initiation of instructional activities; and

Remain in communication with the Institutional Biosafety Committee throughout the conduct of the project.

Responsibilities of the Principal Investigator Prior to Initiating Research

The Principal Investigator shall:

Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken;

Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents; and inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).

Responsibilities of the Principal Investigator During the Conduct of the Research

The Principal Investigator shall:

Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed;

Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the Biological Safety Officer (where applicable), Greenhouse/Animal Facility Director (where applicable), the Institutional Biosafety Committee, NIH/ORDA, and other appropriate authorities (if applicable). Reports to the NIH/ORDA shall be sent to the Office of Recombinant DNA Activities, National Institutes of Health, Suite 323, 6006 Executive Boulevard, MSC 7052, Bethesda, Maryland 20892-7052, (301) 496-9838.

The Institutional Biosafety Committee Chair must be notified immediately. The Chair will immediately notify the Biological Safety Officer and the Provost/Vice President for Academic Affairs with whom reporting to the NIH/ORDA will be coordinated to meet the 30 day reporting requirement. Documentation of notification must be provided by the VPAA to the Principal Investigator no later than 27 days after the incident.

Correct work errors and conditions that may result in the release of recombinant DNA materials; and

Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics).

Standard Practices and Training

The first principle of containment is strict adherence to good microbiological practices (see Appendices G-III-A through G-III-J of the NIH Guidelines). Consequently, all personnel directly or indirectly involved in experiments using recombinant DNA shall receive adequate instruction (see Sections IV-B-1-e and IV-B-4-d of the NIH Guidelines). At a minimum, these instructions include training in aseptic techniques and in the biology of the organisms used in the experiments so that the potential biohazards can be understood and appreciated.

The Laboratory Safety Monograph (see Appendix G-III-O of the NIH Guidelines) and Biosafety in Microbiological and Biomedical Laboratories (see Appendix G-III-B of the NIH Guidelines) describe practices, equipment, and facilities in detail.

Shipment

Shipping regulations as specified in the NIH Guidelines, Appendix H, p. 38 must be followed.

Review Procedure

Investigators planning to perform recombinant DNA experiments or instructional activities must complete the Institutional Biosafety Committee Notification Form (attachment 3) whether or not they consider the project to be exempt from the biosafety regulations. The form should be submitted to the IBC Chair, c/o Office of Sponsored Programs, HAB 805, along with a copy of the research/activity proposal one month prior to proposal submission or planned initiation of project activities. The Committee will be convened at the discretion of the IBC chair to consider the proposed experiment. Determination of exempt status may be made by the Chair or one or two experienced reviewers. Notification of the results of IBC review

will be sent to the investigator. Formal notification of exempt reviews will be reported to all committee members within 30 days with a copy sent to the Office of Sponsored Programs.

Record/Document Maintenance

Administrative support for the Institutional Biosafety Committee will be provided by the Office of Sponsored Programs. Copies of the policy statement and the notification form will be maintained in this office and sent to investigators upon request. Minutes of meetings and copies of review results will be maintained by this office.

Institutional Biosafety Committee Criteria for Evaluating Recombinant DNA Experiments

The monitoring levels described below (A-C) are a brief summary of Section III of the Federal Register June 24, 1994 regulations (NIH Guidelines) with page references for important points.

The NIH Guidelines distinguish 5 levels of monitoring for recombinant DNA experiments (page 6-10). Each level of monitoring has suggested physical containment levels.

Physical containment levels are summarized on the **Institutional Biosafety Committee Notification Form** (Attachment 3) and can be found in the NIH Guidelines Appendix G (pages 29-38).

SUNY New Paltz allows only experimental and instructional activities which are to be conducted at levels no higher than BL1 containment (see Attachment 2 describing containment for BL1).

Non-permissible Experiments

The experiments described in Sections IIIA, IIIB and IIIC in the NIH Guidelines **may not** be conducted at SUNY New Paltz. They are summarized below, for reference only.

Section IIIA:

These experiments involve use of recombinant DNAs to transfer drug resistance to organisms that are not known to acquire it naturally or transfer recombinant DNA into human subjects.

Section IIIB:

These experiments involve the cloning of toxin molecules with an LD₅₀ of less than 100 nanograms per kilogram of body weight and human gene transfer experiments.

Section IIIC:

These experiments use human or animal pathogens (Classes 2-5, pages 20-23 of the NIH Guidelines) as host/vector systems. Also included are experiments in which DNA from human or animal pathogens (Classes 2-5, listed on p. 20-23) is transferred into nonpathogenic prokaryotes or lower eukaryotes (with specific exceptions that are exempt) and experiments with infectious animal or plant viruses in tissue culture or defective viruses with a helper virus. Other experiments in this category, involving whole animal or plant experiments, are recommended for BL1 containment but the level can be set higher by the IBC if desired. This category also includes experiments involving more than 10 liters of culture with recombinant DNA in the cells and human gene transfer experiments not covered in Sections IIIA and IIIB.

Permissible Experiments

Section IIID:

The experiments in Section IIID are to be conducted at BL1 unless judged to require a higher level of containment. Experiments in Section IIID include (1) those not covered in Sections IIIA-C and E, (2) those that involve recombinant DNA molecules composed of no more than 2/3 of a eukaryotic viral genome propagated and maintained in tissue culture, and (3) those that involve whole plants (experiments that do not fall into Section IIIA-C or E).

Section IIIE:

The experiments in Section IIIE are exempt from the guidelines. Exempt experiments include: (1) molecules that are not in an organism or virus (i.e. tissue culture experiments), (2) DNA from only one nonchromosomal or viral DNA (i.e. plasmids), (3) prokaryotic virus/host combinations that occur naturally, (4) eukaryotic DNA propagated in the same eukaryote, (5) recombinant DNAs that could be formed by naturally occurring exchanges between the organisms involved and (6) specifically exempted experiments (see below).

Specifically Exempted Experiments (Summarized from Appendix C, NIH Guidelines)

The following classes of experiments are exempt under Section IIIE-6. Exceptions for each exempt category are specified in Appendix C, NIH Guidelines and in the 1996 amendments to the guidelines.

- Experiments with recombinant DNA molecules containing less than half of any eukaryotic viral genome propagated and maintained in tissue culture.
- Experiments with *E. coli* K-12 host-vector systems provided that the host does not contain conjugative plasmids or generalized transducing phages. Lambda, lambdoid or Ff bacteriophages or non-conjugative plasmids shall be used as vectors. However, the *E. coli* host conjugative plasmid system may be used when the inserted DNA is naturally shared between prokaryotic systems. For these experiments BL1 containment is suggested. If these experiments involve any of the designated items form 111A or B categories, they take precedence over the exemption.
- Experiments with the *Saccharomyces cerevisiae* host-vector systems or *S. uvarum* except for the ones described in IIIA, IIIB and those involving DNA from Class 3, 4 & 5 organisms. Experiments with *S. cerevisiae* involving large scale experiments and the cloning of toxin producing genes is prohibited.
- Experiments with the *Bacillus subtilis* or *Bacillus licheniformis* host-vector system if it is an asporogenic strain that does not revert to sporulation more than once in 10^7 cells, except if described in IIIA, IIIB or if DNA is used from Class 3, 4, or 5 organisms.
- Experiments involving vectors of gram positive organisms listed on pages 25-26 of the NIH Guidelines are exempt unless covered by IIIA or B.

Note: If an experiment falls into either Section IIIA or Section IIIB and one of the other categories, the rules pertaining to Section IIIA or Section IIIB shall be followed. If an experiment falls into Section IIIE and into either Sections IIIC or IIID categories as well, the experiment is considered exempt from the NIH Guidelines.

BIOSAFETY LEVEL 1 (BL1 – From pages 29-30, NIH Guidelines)

1. Standard microbiological practices (BL1)
 - a. Access to the laboratory is limited or restricted at the discretion of the Principal Investigator when experiments are in progress.
 - b. Work surfaces are decontaminated once a day and after any spill of viable material.
 - c. All contaminated liquid or solid wastes are decontaminated before disposal.
 - d. Mechanical pipetting devices are used; mouth pipetting is prohibited.
 - e. Eating, drinking, smoking, and applying cosmetics are not permitted in the work area. Food may be stored in cabinets or refrigerators designated and used for this purpose only.
 - f. Persons wash their hands; (i) after they handle materials involving organisms containing recombinant DNA molecules and animals, and (ii) before exiting the laboratory.
 - g. All procedures are performed carefully to minimize the creation of aerosols.
 - h. In the interest of good personal hygiene, facilities (e.g., hand washing sink, shower, changing room) and protective clothing (e.g., uniforms, laboratory coats) shall be provided that are appropriate for the risk of exposure to viable organisms containing recombinant DNA molecules.
2. Special Practices
 - a. Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak-proof container which is closed before being removed from the laboratory.
 - b. An insect and rodent control program is in effect.
3. Containment Equipment
 - a. Special containment equipment is generally not required for manipulations of agents assigned to BL1.
4. Laboratory Facilities
 - a. The laboratory is designed so that it can be easily cleaned.
 - b. Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

- c. Laboratory furniture is sturdy. Spaces between benches, cabinets, and equipment are accessible for cleaning.
- d. Each laboratory contains a sink for hand washing.
- e. If the laboratory has windows that open, they are fitted with fly screens.

INSTITUTIONAL BIOSAFETY COMMITTEE NOTIFICATION FORM

Investigators and professors who plan to perform recombinant DNA experiments are required to fill out this form whether or not they consider their experiment to be exempt from the NIH Guidelines for Recombinant DNA. The form should be submitted to the IBC chair, care of the Office of Sponsored Programs (HAB 805), along with a copy of the research proposal or instructional experimental design one month prior to proposal submission or initiation of instructional activities. The Committee will then be convened at the discretion of the IBC chair to consider the proposed experiment(s).

Name _____

Principal Investigator (PI) on grant, if different _____

Course in which used, if applicable _____

Proposed start date _____

Persons to be involved in carrying out the project _____

Source of the DNA:

Nature of the inserted DNA sequences:

Hosts and vectors to be used:

Will an attempt to obtain gene expression of a foreign gene be part of this experiment?
If so, describe the protein product that will be produced.

What containment conditions are you planning to use (circle one):

Descriptions of Biological Safety Levels:

BL1: General aseptic technique, waste sterilization before discard. Training of personnel. Knowledge of specific practices required, for example hand washing and no eating or drinking. Specific practices are listed in Attachment 2.

BL2: Posting area, restricted access, general aseptic techniques, waste sterilization in special closed container before discard. Lab coats. Other items listed in BL1. **Not to be performed at SUNY New Paltz.**

BL3: BL2 practices plus controlled access during experiments, special biohazard training and awareness, biological safety cabinets or other physical containment when living organisms contain recombinant DNAs, masks in animal rooms, and other measures. **Not to be performed at SUNY New Paltz.**

BL4: Maximum containment laboratory. **Not to be performed at SUNY New Paltz.**

Briefly describe the personnel training to be used for this project:

I am aware that the PI is responsible to perform the following (guidelines summarized from pages 13-14 of NIH Guidelines and the SUNY New Paltz Policy Statement on Research Involving Recombinant DNA Molecules):

1. Acquire IBC approval, follow appropriate procedures, report problems as described in the SUNY New Paltz Policy Statement, report changes, be trained, adhere to emergency plans, and comply with shipping requirements of recombinant DNA.
2. Communicate with NIH/ORDA concerning new host vector systems, proposed exemptions, approval of Section IIIA & IIIB experiment, case-by-case reviews and experiments not covered in the guidelines.
3. Make initial determination of containment levels, select techniques, submit research protocol and changes to IBC and remain in communication with IBC.
4. Make lab staff aware of protocols, hazards and precautions; instruct and train; inform staff of any precautionary medical practices.

5. Supervise safety and performance of lab, report significant problems, correct errors, ensure integrity of equipment and organisms.
6. Resubmit a renewal form (Attachment 4) annually.

I verify that all of the information on this notification form is correct and I agree to adhere to the PI responsibilities.

Signature

Date

INSTITUTIONAL BIOSAFETY COMMITTEE NOTIFICATION FORM – RENEWAL

Investigators and professors who plan to perform recombinant DNA experiments are required to fill out this form whether or not they consider their experiment to be exempt from the NIH Guidelines for Recombinant DNA. The form should be submitted to the IBC chair, care of the Office of Sponsored Programs (HAB 805), along with a copy of the research proposal or instructional experimental design one month prior to proposal submission or initiation of instructional activities. The Committee will then be convened at the discretion of the IBC chair to consider the proposed experiment(s).

Name _____

Principal Investigator (PI) on grant, if different _____

Course in which used, if applicable _____

Renewal dates _____

Persons to be involved in carrying out the project _____

Has the project changed with regard to the source of DNA, inserted DNA sequences, host or vectors to be used?

Has the project changed with regard to attempts to produce a protein product?

_____ Yes – Please submit attachment 3

_____ No

Please note any problems that have arisen.

Signature _____

Date _____

6/3/96