SUNY NEW PALTZ
Policy Statement

RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (R/SNAM)

SUNY New Paltz is committed to the safe conduct of experiments involving recombinant or synthetic nucleotides 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 regulations are implemented. SUNY New Paltz (and the Institutional Biosafety Committee (IBC) acting on its behalf) takes the responsibility for ensuring that recombinant synthetic nucleotide activities comply with the intent as well as the specifics of the National Institutes of Health "Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines), April 2019" and all subsequent amendments. The New Paltz Policy Statement regulations supersede NIH Guidelines.

Applicability

This policy applies to funded and non-funded, experimental or instructional projects involving recombinant or synthetic nucleotides conducted by students, faculty, staff or affiliate researchers on campus or off campus. The policy covers ALL activities involving recombinant or synthetic nucleotides 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.

Definitions

Recombinant and synthetic nucleic acids are defined as:
(i) molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids;
(ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
(iii) molecules that result from the replication of those described in (i) or (ii) above.

Laboratory work involving small DNA molecules such as oligonucleotides, PCR primers, PCR products, and nucleic acid probes do not require registration with IBC if the following applies: Those synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA

polymerase), and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. Additional exempt activities are described in Section III-F of the NIH Guidelines.

Allowable Activities

Allowable research and other experimental or instructional activities are limited to those which may be conducted within containment levels no higher than BL2 (using Risk Group 1 and 2 organisms), and only in appropriate laboratory facilities. Exempt Experiments (described in III-F of the NIH Guidelines) do not require IBC notification. Activities described in III-D and III-E require review at least one month prior to initiation.

Unallowable Activities vs prohibited

Activities described in III-A, III-B and III-C are not allowable.

No recombinant or synthetic nucleotide experiments are to be conducted with human subjects.

No experiments necessitating a health surveillance program are to be conducted. No recombinant or synthetic nucleotide experiments are to be conducted utilizing plants.

No recombinant or synthetic nucleotide experiments are to be conducted utilizing animals without review and approval by the Institutional Animal Care and Use Committee (IACU) and the IBC. No experiments involving the deliberate release of transgenic animals (or animals that have had recombinant or synthetic nucleic acid molecules administered to them) into the environment are to be conducted. The IACU review shall examine the Biosafety Level restrictions and associated containment procedures for the animal activities. Experiments requiring containment principles described in Appendix M of the NIH Guidelines are not allowable.

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. A request for exemption in such a case must be submitted to the ICB at least one month prior to initiation.

All recombinant or synthetic nucleotide activities must adhere to the appropriate physical containment as described in Appendix G of the NIH Guidelines. Principle Investigators must familiarize themselves with The Laboratory Safety Monograph and on the OSP web site and Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition (and on the OSP web site). These documents describe 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.

Roles and Responsibilities

Responsibilities of the Institution

Each institution conducting or sponsoring recombinant or synthetic nucleotide 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 or synthetic nucleotide 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 (IBC) that meets the requirements and carries out the functions detailed in the NIH Guidelines.

Provide administrative support for the Institutional Biosafety Committee through the Office of Sponsored Programs and Research Compliance.

Assist and ensure compliance with the NIH Guidelines by Principal Investigators conducting research at the institution as specified in Section IV-B-7 (Roles and Responsibilities, PI) of the NIH Guidelines.

Ensure appropriate training for the Institutional Biosafety Committee Chair and members, Biological Safety Officer (when applicable, i.e. when BL3 and above activities are performed), 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 and students are appropriately trained.

Appoint a Biological Safety Officer and communicate any duties associated with recombinant or synthetic nucleotide activities, when applicable.

Report any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to NIH OSP within thirty days. Reports shall be sent to the Office of Science Policy, National Institutes of Health, preferably by e-mail to: NIHGuidelines@od.nih.gov; additional contact information is also available on the OSP website (www.osp.od.nih.gov).

Responsibilities of the Institutional Biosafety Committee (IBC)

The institution shall establish an Institutional Biosafety Committee whose responsibilities need not be restricted to recombinant or synthetic nucleotides. 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 or synthetic nucleotides technology and the capability to assess the safety of recombinant or synthetic nucleotides 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).

In order to ensure the competence necessary to review and approve recombinant or synthetic nucleotides activities, it is recommended that the Institutional Biosafety Committee: (1) include persons with expertise in recombinant or synthetic nucleotides 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 OSP 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 OSP.

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/they 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 or synthetic nucleotides, the chair will appoint an 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 in 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 Science Policy, National Institutes of Health, preferably by e-mail to: NIHGuidelines@od.nih.gov; additional contact information is also available on the OSP website (www.osp.od.nih.gov).

Functions

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

Annual review of recombinant or synthetic nucleotide 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 or synthetic nucleotide research.

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-D-2-a of the NIH Guidelines. Setting containment levels as specified in Sections III-D-4-b. Setting containment levels as specified in Section III-D-4-b (Experiments Involving Whole Animals).

Annual review of recombinant or synthetic nucleotide 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 or synthetic nucleotide research.

The IBC Chair is responsible for ensuring that Institutional Biosafety Committee members are appropriately trained.

The IBC Chair 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 with whom reporting to NIH/ORDA, if required, will be coordinated to meet the 30 day reporting requirement. Reports to NIH OSP shall be sent to the Office of Science Policy, National Institutes of Health, preferably by e-mail to: NIHGuidelines@od.nih.gov; additional contact information is also available on the OSP website (www.osp.od.nih.gov).

The Institutional Biosafety Committee may not authorize initiation of experiments which are not explicitly covered by the NIH Guidelines until the 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-b of the NIH Guidelines.

Principal Investigator

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

General Responsibilities

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

Adhere to Institutional Biosafety Committee-approved emergency plans for handling accidental spills and personnel contamination as described in The Laboratory Safety Monograph and Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition

Will not initiate or modify recombinant or synthetic nucleic acid research which, as described by the NIH Guidelines and this policy statement, requires Institutional Biosafety Committee approval before initiation (see Allowable Activities described in this Policy Statement) 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;

Submit a Research/Instruction Involving Recombinant and Synthetic Nucleic Acid Molecules Notification Form for all experiments covered by Section III-D, E or F of the NIH Guidelines;

Ensure that laboratory staff and students are appropriately trained and that the appropriate procedures are followed;

Immediately report any significant problems, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to the IBC Chair and Biological Safety Officer (where applicable), IACUC chairperson (where applicable), Institutional Biosafety Committee, NIH OSP and other appropriate authorities (if applicable) within 30 days. Reports to the NIH OSP shall be sent to the Office of Science Policy, National Institutes of Health, preferably by e-mail to: NIHGuidelines@od.nih.gov; additional contact information is also available on the OSP website (www.osp.od.nih.gov). The IBC Chair will immediately notify the Biological Safety Officer, The Director of Sponsored Programs and Research Compliance and the Provost, with whom reporting to the NIH OSP, if required, will be coordinated to meet the 30 day reporting requirement. Documentation of notification must be provided by the Provost to the Principal Investigator no later than 27 days after the incident. The IBC Chair will also, through the Office of Sponsored Programs and Research Compliance, notify the IBC members.

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

Be adequately trained in good microbiological techniques.
Comply with shipping requirements for recombinant/ synthetic DNA molecules (see Appendix H of the NIH Guidelines for shipping requirements and the Laboratory Safety Monograph for technical recommendations).

Submit information to NIH OSP for certification of new host-vector systems, after prior notice to ICB; Petition NIH OSP, after prior 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 (Section IV-B-7).

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 to the Institutional Biosafety Committee for review and approval or disapproval at least 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, as needed.

Responsibilities of the Principal Investigator Prior to Initiating Research

The Principal Investigator shall:
Make available to all laboratory staff and students the protocols that describe the potential biohazards and the precautions to be taken;

Instruct and train laboratory staff and students in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents; and inform the laboratory staff and students 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 IBC Chair and Biological Safety Officer (where applicable), IACUC chairperson (where applicable), Institutional Biosafety Committee, NIH OSP and other appropriate authorities (if applicable) within 30 days. Reports to the NIH OSP shall be sent to the Office of Science Policy, National Institutes of Health, preferably by e-

mail to: NIHGuidelines@od.nih.gov; additional contact information is also available on the OSP website (www.osp.od.nih.gov). The IBC Chair will immediately notify the Biological Safety Officer, The Director of Sponsored Programs and Research Compliance and the Provost, with whom reporting to the NIH OSP, if required, will be coordinated to meet the 30 day reporting requirement. Documentation of notification must be provided by the Provost to the Principal Investigator no later than 27 days after the incident. The IBC Chair will also, through the Office of Sponsored Programs and Research Compliance, notify the IBC members.

Correct work errors and conditions that may result in the release of recombinant or synthetic nucleotide 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 Appendix G of the NIH Guidelines). Consequently, all personnel directly or indirectly involved in experiments using recombinant or synthetic nucleotides shall receive adequate instruction (see Institutional and Principal Investigator sections of this policy). 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 and Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition describe practices, equipment, and facilities in detail.

Shipment

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

Review Procedure

Investigators planning to perform recombinant or synthetic nucleotide experiments or instructional activities must complete the Institutional Biosafety Committee Notification Form whether or not they consider the project to be exempt from NIH Guidelines. The form should be submitted electronically (or by mail) to the IBC Chair, c/o Office of Sponsored Programs and Research Compliance (ibc@newpaltz.edu) at least 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 and the Office of Sponsored Programs and Research Compliance. Formal notification of exempt reviews will be reported to all IBC members within 30 days by the Office of Sponsored Programs and Research Compliance.

Record/Document Maintenance

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

Non-permissible Experiments

The experiments described in Sections IIIA, IIIB and IIIC in the NIH Guidelines **shall not** be conducted at SUNY New Paltz.

The experiments described in Section IIID-1, except those involving Risk Group 2 bacterial agents as host/vector systems and as described in Section III-D-1-a. (Experiments involving the introduction of recombinant or synthetic nucleic acid molecules into Risk Group 2 agents will usually be conducted at Biosafety Level (BL) 2 containment).

Definitions:
Risk Group 1 (RG1) - Agents that are not associated with disease in healthy adult humans. This group includes a list of animal viral etiologic agents in common use. These agents represent no or little risk to an individual and no or little risk to the community. See Appendix B-I, NIH Guidelines.
Risk Group 2 (RG2) - Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available. These agents represent a moderate risk to an individual but a low risk to the community. See Appendix B-II, NIH Guidelines.
BIOSAFETY LEVEL 1 (BL1 – From Appendix G-II, NIH Guidelines)

1. Standard microbiological practices
    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 or kept in the locked position.

BIOSAFETY LEVEL 2 (BL2 – From Appendix G-III-N, NIH Guidelines)

Biosafety Level 2 is similar to Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs in that: (1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists; (2) access to the laboratory is limited when work is being conducted; and (3) certain procedures in which infectious aerosols are created are conducted in biological safety cabinets or other physical containment equipment (see Appendix G-III-A, *Footnotes and References of Appendix G*)

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