Stony Brook University

Institutional Biosafety Committee (IBC)
By-Laws

March 2016

This institution has an Institutional Biosafety Committee (IBC) whose responsibilities include review of recombinant or synthetic nucleic acid molecule (rsNAM) research. These by-laws complement SBU's Institutional Policy on Research Involving rsNAMs (http://research.stonybrook.edu/sites/default/files/IBC%20POLICY.pdf), which describes the procedures that the Institutional Biosafety Committee follows in its initial review, approval, and oversight of applications, proposals, and activities.

The SBU website for Biosafety in Research (http://research.stonybrook.edu/biosafety) provides links to the current IBC membership roster, meeting dates, submission deadlines, and links to institutional policies and procedures, NIH Guidelines, and other information relevant to the compliant conduct of rsNAM at SBU.

The IBC is administered by the Office of Research Compliance, within the Office of the Vice President for Research. The institutional official responsible for oversight of the IBC is the Vice President for Research (VPR), who delegates this responsibility to the Assistant Vice President for Research Compliance.

The IBC is in compliance with the requirements of the NIH Guidelines for Research Involving rsNAM ("NIH Guidelines"; some appendices referenced below) and meets the following requirements:

Membership

The Institutional Biosafety Committee is comprised of no fewer than five members, appointed by the Vice President for Research, who are selected so that they collectively have experience and expertise in recombinant or synthetic nucleic acid molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule research and to identify any potential risk to public health or the environment. The membership includes:

- At least two members that are not affiliated with the institution (apart from their membership on the Institutional Biosafety Committee) and 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).
- At least one individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments utilizing Appendix P, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants*, require prior approval by the Institutional Biosafety Committee.
- At least one scientist with expertise in animal containment principles when experiments utilizing Appendix Q, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals*, require Institutional Biosafety Committee prior approval.
- As Stony Brook conducts certain rsNAM activities (e.g., requiring BSL3 containment), a Biological Safety Officer is a member of the Institutional Biosafety Committee.
- As Stony Brook participates in rsNAM research involving human research participants, the IBC ensures that committee membership (or consultants to the IBC) includes adequate expertise and training, including an individual with expertise in human gene transfer principles, all aspects of Appendix M have been appropriately addressed by the Principal Investigator; no research participant will be enrolled in a human gene transfer experiment until the RAC review process has been completed, and (iv) final IBC approval is granted only after the RAC review process has been completed. IBC approval must be obtained from the institution at which recombinant or

synthetic nucleic acid molecule material will be administered to human research participants (rather than the site involved in manufacturing gene transfer products).

- In order to ensure the competence necessary to review and approve recombinant or synthetic nucleic acid molecule activities, the Institutional Biosafety Committee considers that the membership or consultants include: (i) persons with expertise in recombinant or synthetic nucleic acid molecule technology, biological safety, and physical containment; (ii) persons knowledgeable in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment, and (iii) include at least one member representing the laboratory technical staff.

Members who are unable to regularly attend convened meetings of the IBC will be replaced with new members at the recommendation of the chair to the VPR or his/her designee.

Annual Report to NIH/Office of Biotechnology Activities
Stony Brook files an annual report with NIH/OBA which includes: (i) a roster of all Institutional Biosafety Committee members clearly indicating the Chair, contact person, Biological Safety Officer (if applicable), plant expert (if applicable), animal expert (if applicable), human gene therapy expertise or *ad hoc* consultant (if applicable); and (ii) biographical sketches of all Institutional Biosafety Committee members (including community members).

Conflict of Interest
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, has a direct financial interest, or has any other relationship to the activity which could reasonably be considered a real or apparent conflict of interest.

Public Considerations
Depending on specific circumstances, and consistent with protection of privacy and proprietary interests of investigators and the institution, SBU will allow the public to attend its IBC meetings. Such a decision will be made in consultation with applicable Institutional entities, including legal counsel.

Upon request, SBU will 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. Office of Research Compliance, Office of Internal Audit, legal counsel, and others as required will assess the need to redact certain (e.g., proprietary, personal etc.) information prior to release of the document(s) in question.

IBC Responsibilities

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

- Reviewing recombinant or synthetic nucleic acid molecule research conducted at or sponsored by the institution for compliance with the *NIH Guidelines* as specified in Section III, *Experiments Covered by the NIH Guidelines*, and approving those research projects that are found to conform with the *NIH Guidelines*. This review include:
    - Independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research;
    - Assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant or synthetic nucleic acid molecule research;
    - And for human gene transfer experiments,
        - ensuring that all aspects of Appendix M have been appropriately addressed by the Principal Investigator;
        - ensuring that no research participant is enrolled (see definition of enrollment in Section I-E-7) in a human gene transfer experiment until the RAC review process has been completed (see Appendix M-I-B, *RAC Review Requirements*), Institutional Biosafety Committee approval (from the clinical trial site) has been

obtained, Institutional Review Board approval has been obtained, and all applicable regulatory authorizations have been obtained;
    - for human gene transfer protocols selected for public RAC review and discussion, consideration of the issues raised and recommendations made as a result of this review and consideration of the Principal Investigator's response to the RAC recommendations;
    - ensuring that final IBC approval is granted only after the RAC review process has been completed (see Appendix M-I-B, *RAC Review Requirements*); and
    - ensuring compliance with all training, surveillance, data reporting, and adverse event reporting requirements set forth in the *NIH Guidelines*.

- 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, *Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems*.

- Setting containment levels as specified in Sections III-D-4-b, *Experiments Involving Whole Animals*, and III-D-5, *Experiments Involving Whole Plants*.

- Periodically reviewing recombinant or synthetic nucleic acid molecule research 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 nucleic acid molecule research. See the SBU document titled 'Policy and Procedures for Incidents Involving Recombinant or Synthetic Nucleic Acid Molecules (rsNAM) an Materials'

- Reporting any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses per SBU Policy and Procedures for Research Involving rsNAM, Section VI.

- The Institutional Biosafety Committee will 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, *Institutional Biosafety Committee*.

Biological Safety Officer (BSO)

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

- Periodic inspections to ensure that laboratory standards are rigorously followed;

- Reporting to the Institutional Biosafety Committee and the institution 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;

- Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant or synthetic nucleic acid molecule research;

- Providing advice on laboratory security;

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

Plant, Plant Pathogen, or Plant Pest Containment Expert

When the institution conducts recombinant or synthetic nucleic acid molecule research that requires Institutional Biosafety Committee approval in accordance with Appendix P, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Plants*, the institution shall appoint at least one individual with expertise in plant, plant pathogen, or plant pest containment principles (who is a member of the Institutional Biosafety Committee).

Animal Containment Expert

When the institution conducts recombinant or synthetic nucleic acid molecule research that requires Institutional Biosafety Committee approval in accordance with Appendix Q, *Physical and Biological Containment for Recombinant or Synthetic Nucleic Acid Molecule Research Involving Animals*, the institution shall appoint at least one individual with expertise in animal containment principles (who is a member of the Institutional Biosafety Committee).

Human Gene Therapy Expertise

When the institution participates in or sponsors recombinant or synthetic nucleic acid molecule research involving human subjects, the institution must ensure that: (i) the Institutional Biosafety Committee has adequate expertise and training (using *ad hoc* consultants as deemed necessary) and (ii) all aspects of Appendix M, *Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant or Synthetic Nucleic Acid Molecules into One or More Human Subjects (Points to Consider)*, have been appropriately addressed by the Principal Investigator prior to submission to NIH/OBA.