SUNY ESF Institutional Bio-Safety Committee (IBC)

Policy and Procedures

I. Policy

All research conducted at or sponsored by SUNY ESF or conducted by employees of SUNY ESF which involves the use of infectious agents, fresh human tissue, blood, non- native species requiring USDA-APHIS permits, or recombinant DNA must be reviewed by the Institutional Biosafety Committee ('IBC'). Work with recombinant DNA must be conducted in accordance with NIH Guidelines (https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html)

All persons working in laboratories that deal with these substances must be informed of the potential hazard and instructed in the procedures needed to avoid exposure and infection as applicable. It is the responsibility of the principal investigator to inform and instruct those persons under his/her supervision and maintain documentation.

The IBC is authorized to inspect research facilities, approve research practices and procedures, and to take actions, such as enforcement or cessation of research or instructional activities in the event of an unsafe workplace/instructional situation.

If an ESF investigator is conducting recombinant DNA research at another institution, an application must be submitted to the IBC only if the research is supported by funds administered by the Research Foundation of SUNY or other campus-related organizations. In any case, approval of the IBC at the host institution must be obtained prior to initiation of the activity.

IBC Composition:
The IBC is composed of a minimum of 5 members. At least two members shall be unaffiliated with SUNY ESF (apart from their membership on the IBC) to represent the interest of the surrounding community, with respect to health and protection of the environment; at least one member shall be a

scientist with expertise in recombinant DNA technology and physical containment; and the Institutional Biological Safety Officer.

No member of the IBC may be involved (except to provide information requested by the 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.

II. Definitions

A. Recombinant DNA molecules:

(1) 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

(2) molecules that result from the replication of those described in (1) above.

Note:

1. 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 vivoas a biologically active polynucleotide or polypeptide product, it is exempt from the NIH Guidelines.

2. 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 NIH Guidelines unless the transposon itself contains recombinant DNA.

B. Human gene transfer research:

Research involving the deliberate transfer of recombinant DNA, or DNA or RNA derived from recombinant DNA into the somatic cells of human subjects.

C. Biohazardous Materials:

Pathogens or tissues capable of holding such pathogens at or above CDC defined Biosafety Level 2 or recombinant DNA molecules as defined by the NIH Guidelines.

III. Procedures for Reviewing Recombinant DNA Research

Review by the IBC shall include: (i) independent assessment of the containment levels required by the NIH Guidelines for the proposed research; (ii) assessment of the facilities (a site visit may be required), procedures, practices, and training and expertise of personnel involved in recombinant DNA research.

The IBC will notify the Principal Investigator of the results of the Institutional Biosafety Committee's review, by mail or e-mail.

A. The various types of recombinant DNA experiments, as well as the relevant approval/notification requirements, are outlined in:

(1) the IBC application, available for viewing or downloading at http://www.esf.edu/ CORRECT THIS LINK

and

(2)the NIH guidelines, available at:
https://osp.od.nih.gov/biotechnology/nih-guidelines/

B. Submission of an application, biosafety manual, grant and grant summary (if external funding is being sought) to the IBC is required for all experiments involving recombinant DNA, *including those falling into the 'exempt' experiment category.*

(1) If the application indicates that the proposed experiments are exempt or require only notification (not approval) to the IBC, the IBC Chair or his/her designee will review the materials for confirmation of investigator assessment. The investigator will be notified in writing if further information is required, or if the document is acceptable as written. An approval date will be issued for administrative purposes, so that category status of the research activity can be confirmed upon renewal.

(2) If the application indicates that approval (local, or local and federal) is required, review will be conducted at a convened meeting of the IBC consisting of a quorum of members. Action will be determined by a simple majority of votes. The investigator will be notified in writing if further information is required, or if the document is approved. Approval will be granted for a maximum of one year, at which time the PI must submit a progress report to the IBC.

IV. Procedures for Reviewing Research Involving Infectious or Biohazardous Agents/Tissues

Submission of an application, biosafety manual, grant and grant summary (if external funding is being sought) to the IBC is required for all experiments involving infectious or biohazardous agents.

Review of the project shall include: (i) assessment of the containment levels required; and (ii) assessment of the facilities (a site visit may be required), procedures, practices, and training of personnel involved in the research.

The IBC Chair or his/her designee will review the materials for confirmation of investigator assessment. The investigator will be notified in writing if further information is required, or if the document is acceptable as written. An approval date will be issued, so that tracking for annual renewal can be initiated.

All related work must comply with the *"SUNY ESF Institutional Biosafety Committee: Guidance on the Use of Human, Primate, and Mammalian Cell Lines"*. (LINK)

V. Procedures for Reviewing Research Involving the Importation of Non-native Organisms

Submission of an application, biosafety manual, relevant government permits, grant and grant summary (if external funding is being sought) to the IBC is required for all use of non-native organisms (including organisms native to NYS, but being transported across State lines) regulated by USDA-APHIS, US-FWS, and state agencies such as NYS Dept. Agric. & Markets.

Review of the project shall include: (i) assessment of the containment levels required; and (ii) assessment of the facilities (a site visit may be required), procedures, practices, and training of personnel involved in the research.

The IBC Chair or his/her designee will review the materials for confirmation of investigator assessment. The investigator will be notified in writing if further information is required, or if the document is acceptable as written. An approval date will be issued, so that tracking for annual renewal can be initiated.

VI. Continuing Review of IBC approved Projects

PI's must perform an annual review of all projects which have been reviewed and approved by the IBC. A *Progress Report* form (LINK) must be submitted to the IBC for review at least one week prior to the project's expiration date. The Committee will re-review all approved research every five years to ensure compliance with the NIH and Institutional Guidelines. Investigators will be asked to submit an updated Application Form, Bio-Safety Manual and Personnel form, for the five year review.

VII. Amendments to Approved Projects

Prior to implementing any changes to an approved project (including exempt research), the PI will submit an amendment to the IBC and await approval from the IBC Chair, his/her designee, and/or IBC Committee. Amendments will be reviewed by the Chair or an IBC member designated by the Chair and may be referred to the full committee for review if there is a change in risk to the public or employees or if required by the NIH guidelines.

VIII. Investigator's Responsibility

The IBC requires compliance with Principal Investigator's Responsibilities, as outlined in the NIH Guidelines, section IV.B.7, https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948348.

IX. Training Requirements

All employees working with potentially infected substances must participate in training offered by their laboratory supervisor and specific to their hazards and procedures. OSHA Bloodborne Pathogen Standard training may be required training for some employees and is offered by the Environmental Health & Safety Office.

X. Transportation

Transporting Biohazardous (including human blood, body fluids and tissue) Items: Biohazardous items transported in interstate commerce must be transported in accordance with DOT regulations. Biohazardous items being transported from one building to another by SUNY ESF personnel must be transported by labeled (i.e., biohazardous stickers) and sealed (i,.e., locking

handle cooler) secondary containment (i.e., test tube in plastic bag in locking cooler).

XI. Helpful Links:

NIH FAQ's on Recombinant DNA and Gene Transfer
https://osp.od.nih.gov/biotechnology/nih-guidelines-faqs/

NIH Office of Biotechnology Activities
https://osp.od.nih.gov/biosafety-biosecurity-and-emerging-biotechnology/

Risk Group Classification for infectious agents
https://my.absa.org/Riskgroups

American Biological Safety Association
https://absa.org/

Guidance for Regulated Medical Waste Treatment, Storage, Containment, Transport and Disposal. http://www.dec.ny.gov/regulations/8752.html