Upstate Medical University
Institutional Bio-Safety Committee (IBC)

Policy and Procedures for Research Involving Recombinant DNA, and INFECTIOUS OR BIO-HAZARDOUS AGENTS, (Including Human Gene Transfer research)

I. Policy

All research conducted at or sponsored by Upstate Medical University or conducted by employees of Upstate Medical University which involves the use of infectious agents, fresh human tissue, blood, or recombinant DNA must be reviewed by the Institutional Biosafety Committee ('IBC'). Work with recombinant DNA must be conducted in accordance with NIH Guidelines (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html)

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

If an Upstate 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 seven members. At least two members shall be unaffiliated with Upstate (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 animal containment principles; at least two members shall be scientists with expertise in recombinant DNA technology and physical containment; one member shall represent the laboratory technical staff; and the Institutional Biological Safety Officer, with expertise in biological safety, will also be a member of the committee.

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 vivo* as 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 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; (iii) ensuring that all aspects of appendix M (points to consider in the design and submission of protocols for the transfer of recombinant DNA molecules into one or more human research participants) if appropriate, have been appropriately addressed by the Principal Investigator.

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.upstate.edu/researchadmin/ibc/

and

(2) the NIH guidelines, available at http://www4.od.nih.gov/oba/

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.

C. Human Gene Transfer Research

In order for human gene transfer research to be considered, the protocol and consent form approved by the Upstate Medical University Institutional Review Board (IRB) MUST be submitted in addition to the IBC application.

Investigators must review Appendix M of the NIH Guidelines, 'Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant DNA Molecules into One or More Human Subjects'; **(**http://www4.od.nih.gov/oba/), which includes mandated adverse event/safety reporting requirements, whereby investigators who have received approval from the Food and Drug Administration to initiate a human gene transfer protocol must report any serious adverse event immediately to the IRB, IBC, Office for Human Research Protections (OHRP) of the PHS, Office of Biotechnology Activities of NIH, and FDA, followed by the submission of a written report filed with each group.

IV. Procedures for Reviewing Research Involving Infectious or Biohazardous Agents

Submission of an application, biosafety manual, grant and grant summary (if external funding is being sought) to the IBC is required for <u>all</u> 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.

V. Continuing Review of IBC approved Projects

Annual Review of all projects which have been reviewed and approved by the IBC is required. A Progress report form should be submitted to the IBC office for review by the Chair or his/her designee 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.

VI. 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.

VII. Investigator's Responsibility

The IBC requires compliance with Principal Investigator's Responsibilities, as outlined in the NIH Guidelines, section IV.B.7, http://www4.od.nih.gov/oba/. Investigators conducting human gene transfer experiments must additionally accept responsibility for the requirements specified in Appendix M (http://www4.od.nih.gov/oba/) of the Guidelines.

VIII. Training Requirements

All employees working with potentially infected substances must participate in the basic required training for all employees offered by the Department of Environmental Health & Safety, and extended training offered by their laboratory supervisor

IX. Helpful Links:

NIH FAQ's on Recombinant DNA and Gene Transfer
http://www4.od.nih.gov/oba/RAC/RAC_FAQs.htm

NIH Office of Biotechnology Activities
http://www4.od.nih.gov/oba/

Risk Group Classification for infectious agents
http://www.absa.org/XriskgroupsX/index.html

American Biological Safety Association
http://www.absa.org/restool.html

Upstate Environmental Health and Safety
http://www.upstate.edu/ehs/

Upstate Environmental Health and Safety Training Programs
http://www.upstate.edu/ehs/ehs_training.shtml

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Questions concerning this policy/procedure and/or the IBC approval process may be directed to:

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