INSTITUTIONAL BIOSAFETY COMMITTEE

Policy and Procedures for Research Involving Recombinant DNA (Including Human Gene Transfer research)

I.Policy

The National Institutes of Health's Guidelines For Research Involving Recombinant or Synthetic Nucleic Acid Molecules (http://osp.od.nih.gov/office-biotechnology-activities/) and IBC application requirements (see procedure below) are applicable to all faculty, staff, students, and users of the facilities of this University who propose and conduct research involving recombinant DNA or infectious agents.

If a St. John's University 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 St. John's University or other campus-related organizations.

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).

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.

III.Procedure

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

(1) the IBC Investigator self-evaluation, available for viewing or downloading at the SJU Biosafety Webpage.

and

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

B. Submission of a Self-Evaluation is required for all experiments. An application must be submitted to the IBC if the IBC determines that project specific issues and questions exist. This application must include a detailed project description, highlight the safety procedures that will be used and describe any additional resources that will be needed to insure a safe working environment. The IBC will review such applications

on a revolving basis; working with the primary investigator to insure an appropriate research environment is in place before such a project begins.

(1) If the registration materials indicate that the proposed experiments are exempt or require only notification (not approval) to the IBC, the IBC 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 registration materials indicate 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 St. John's University's Institutional Review Board 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://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines) 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 IRB, IBC, Office for Protection from Research Risks of the PHS, Office of Biotechnology Activities of NIH, and FDA, followed by the submission of a written report filed with each group.

IV. IBC-Approved Investigator's Responsibility

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

Submission of registration materials, as well as questions concerning this policy/procedure and/or the IBC approval process may be directed to:

Colleen M. Greaney, Ph. D.
Director, Department of Environmental Health & Safety
Department of Environmental Health & Safety
St.Albert Hall Room G-020
Jamaica, NY 11439

Telephone (718) 990-1348
Email greaneyc@stjohns.edu