Subject: Functions of the Institutional Biosafety Committee for Human Subjects (IBC-HS)

Procedure:
This procedure outlines the functions and operations of the IBC-HS and its coordination with the IRB.

I. Investigator Responsibilities.
   A. When conducting research involving humans, the Investigator submits to the IBC-HS, along with the IRB application, when the proposed research involves:
      1. Experiments involving the deliberate transfer of recombinant DNA or RNA or DNA or RNA derived from recombinant DNA, or synthetic nucleic acids into one or more human subjects;
      2. Experiments utilizing live, recombinant, or attenuated microorganisms for the purposes of vaccination of one or more human subjects;
   B. The Investigator submits an “Application for Research” through the Discovr-e system which contains relevant questions for IBC-HS's evaluation.
   C. In addition, the Investigator may utilize the “Points to Consider: NIH rDNA guidelines” for assistance on the requirements for this type of research activity.
   D. In addition to the information in the IRB Application, the Investigator will submit the following:
      1. The completed “Research Plan” table that identifies the locations and/or responsible party for key protocol elements.
      2. The completed “Clinical Trial Test Article Hazard Profile/Exposure Response Guide” if the PI or personnel may handle a test article containing recombinant DNA molecules or a viable biological agent as part of the preparation, administration, or disposal of such materials.
   E. For Human Gene Transfer research, the information that is required to be provided by the Investigator in the IRB Application includes: (i) the source(s) of DNA; (ii) the nature of the inserted DNA sequences; (iii) the host(s) and vector(s) to be used; (iv) if an attempt will be made to obtain expression of a foreign gene, and if so, indicate the protein that will be produced; and (v) the containment conditions that will be implemented as specified in the NIH Guidelines.
   F. The Investigator forwards any new information identified during IBC-HS or IRB review that alters the risk/benefit ratio for participants, requires a change in the informed consent documents, or alters the proposal in the form of an amendment to the IRB and IBC-HS (See HRPP Policy III.J).

II. IBC-HS review responsibilities.
   A. The IBC-HS reviews the proposed project to assure conformity to the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules along with other federal and state laws for the purposes that include but are including but not limited to:
1. Assessing the potential risk to the environment and public health (e.g., risks to close contacts, health care workers, and the community, as well as the potential participants;
2. Assessing the contamination levels of risk;
3. Assessing the adequacy of facilities, SOPs, and training of PI and KSP;
4. Assessing a plan for adverse event reporting and safety of participants;
Reviewing trial design, biosafety and containment, and compliance with the NIH Guidelines.

B. The IBC-HS along with the IRB collectively decide which studies would benefit from review by the NIH Recombinant DNA Advisory Committee (RAC). Studies where the protocols are:
   1. Using a new vector, genetic material, or delivery method that represents a first in human experience; or
   2. Relying on preclinical safety data that were obtained using a new preclinical model system of unknown or unconfirmed value; or
   3. Using a proposed vector, gene construct, or method of delivery that is associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies to evaluate the protocol rigorously.

III. IRB review responsibilities specific to Human Gene Transfer.
A. The IRB Committees are responsible for evaluating any study involving recombinant or synthetic nucleic acid molecules introduced into humans in conjunction with the HGTBC to assure:
   1. Appropriate risks and potential benefits are adequately outlined in any consent documents;
   2. Recommendations for RAC review have been adequately evaluated; and
   3. All other requirements are met for approval of the research.
B. The IRB Committees may at any time request additional input from the IBC-HS for any submissions of events or document changes that may warrant the expertise of the IBC-HS.

IV. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
A. The RCA screens IRB submissions during the pre-review process to determine if IBC-HS approval is required.
B. The RCA places the new study on the next available agenda IBC-HS, and initiates preparation for IRB review and approval at the level in which the study qualifies.