Subject: Establishment of the Institutional Biosafety Committee for Human Subjects

Definitions:

1. Institutional Biosafety Committee-Human Subjects (IBC-HS): A Committee required by Institutions receiving funding from the National Institutes of Health (NIH) for research involving recombinant DNA molecules. It is further charged with reviewing and approving research conducted with microorganisms pathogenic to humans, plants, or animals. The IBC-HS also provides guidance on the proper acquisition, handling, transfer, and disposal of potentially hazardous or regulated biological materials. The IBC-HS will review those studies where the above listed involves human subjects as participants in the research.

2. Institutional Biological Safety Officer (IBSO): The Biological Safety Officer carries out the duties that include, but are not be limited to: Periodic inspections to ensure that laboratory standards are rigorously followed; Reporting to the IBC-HS and the institution any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses of which the IBSO becomes aware unless it is determined that a report has already been filed by the PI; Assists with developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant or synthetic nucleic acid molecule research; and Providing technical advice to the PI and the IBC-HS on research safety procedures.

3. Human Gene Transfer: The process of transferring into a person recombinant nucleic acid molecules, or DNA/RNA derived from recombinant nucleic acid molecules; synthetic nucleic acid molecules; or DNA/RNA derived from synthetic nucleic acid molecules, that meet any one of the following criteria: contain more than 100 nucleotides; possess biological properties that enable integration into the genome; have the potential to replicate in a cell; or can be translated or transcribed.

4. Recombinant DNA or RNA: DNA or RNA which has been altered from its original form by joining genetic material from two different sources that can replicate in a living cell. It usually involves putting a gene or part of a gene obtained from one organism into the genome of a different organism. The alteration and recombination in the laboratory often involves cutting up DNA or RNA molecules and splicing together specific DNA or RNA fragments. The DNA or RNA may be natural or synthetic. The altered DNA or RNA may be inserted into the receiving DNA or RNA chain by chemical, enzymatic, or biological means.

5. Synthetic nucleic acid molecules: Molecules that are chemically or by other means modified, (i.e., synthesized or amplified) so that they contain functional equivalents of nucleotides that can base pair with naturally occurring nucleic acid molecules. The term refers to the resulting molecules that occur as a result of their replication, as well.

6. Somatic Cell Gene Therapy: The repair or replacement of a defective gene within somatic (body) tissue by administration to humans of autologous, allogenic, or xenogenetic living cells which have been manipulated or processed ex vivo.

7. Recombinant DNA Advisory Committee (RAC): The RAC is the public advisory committee that advises the Department of Health and Human Services (DHHS) Secretary, the DHHS Assistant Secretary for Health, and the NIH Director concerning recombinant or synthetic nucleic acid molecule research.
8. **Office of Science Policy (OSP):** This is the office within the NIH that is responsible for reviewing and coordinating all activities relating to the NIH Guidelines and serve as a focal point for information on recombinant or synthetic nucleic acid molecule activities to provide advice within and outside NIH including institutions, Biological Safety Officers, Principal Investigators, Federal agencies, state and local governments, and institutions in the private sector.

**Policy:**

It is the policy of the Human Research Protections Program (HRPP) to establish the Institutional Biosafety Committee for Human Subjects (IBC-HS) to review the use of gene transfer or therapy in human subjects research, the use of investigational, live, recombinant and/or attenuated microorganism for vaccination or infection, or select agent or toxin research in or with human subjects.

I. **Authority of the IBC-HS.**
   A. The structure, authority, and functions of the IBC-HS are governed by the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. *(See Appendix M)*
   B. The IBC-HS has the authority to review, require modifications, recommend RAC review (along with the IRB), approve or disapprove all research using recombinant or synthetic nucleic acid molecules introduced into humans.
   C. The IBC-HS is registered with the NIH Office of Science Policy (OSP).

II. **IBC-HS Review and Approval.**
   A. Any study that involves materials (i.e., human gene transfer, vaccination, targeted vector or select agents) as defined above in human subjects will require IBC-HS and IRB review and approval.
   B. Research protocols involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid Molecules, into human subjects that meets the criteria as outlined in the NIH Guidelines are reviewed by the IBC-HS, the IRB as well as RAC Review (if applicable).

III. **Composition of the IBC-HS.**
   A. The IBC-HS shall consist of a minimum of five (5) individuals.
   B. The IBC-HS must include the following individuals:
      1. At least (2) individual that represents the community or are otherwise not affiliated with VU or VUMC;
      2. At least (1) individual that has recombinant or synthetic nucleic acid expertise; and
      3. A Biological Safety Officer.

**References:**

NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules Appendix M

HHS and USDA Select Agents and Toxins: 7 CFR 331; 9 CFR 121; 42 CFR 73