Subject: Procedure for Obtaining Biologicals and Human Subjects Subcommittee (BHSS) Approval

Procedure
This procedure provides guidance on obtaining BHSS approval as it pertains to conducting research involving humans under the jurisdiction of the Human Research Protections Program (HRPP).

I. Investigator Responsibilities.
   A. When conducting research involving human gene transfer, the Investigator will consult with the Institutional Biosafety Officer (IBSO) or the Chair of the BHSS.
   B. The BHSS will facilitate the approval processes essential to the conduct of human gene transfer research by working with the Investigators, the IRB, and the IBC to clearly define the necessary steps and develop efficient tools for accomplishing each step. Although not required, Investigators are encouraged to consult with the BHSS for assistance prior to submission to the IRB.
   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 located at [http://grants.nih.gov/grants/policy/select_agent/42CFR_Additional_Requirements.pdf](http://grants.nih.gov/grants/policy/select_agent/42CFR_Additional_Requirements.pdf).
   D. The Investigator will forward any new information identified that alters the risk/benefit ratio for participants, requires a change in the informed consent documents, or alters the IRB approved application and associated documents, in the form of an amendment to the IRB (See HRPP Policy III.J).

II. IRB Committee Responsibilities.
   A. The IRB Committee, IRB Chair, or designated Committee Member will review approvals granted by the BHSS.
   B. The IRB will review human gene transfer research per HRPP policies and procedures, federal regulations and guidelines.
   C. The IRB Committee, IRB Chair, or designated Committee Member may consult with the BHSS for issues requiring their expertise and guidance.
   D. The IRB will proceed with review and approval of the research at the level in which the study qualifies
   E. The IRB does not need to delay final approval pending BHSS review.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
   A. The RCA will screen new IRB submissions during the pre-review process to determine if BHSS review may be recommended. The RCA may confer with the IRB Chair for advice on this recommendation
   B. In the event that the RCA questions the need for BHSS approval he or she will contact the IBSO.
   C. The RCA will place the new study on the next available agenda, regardless of the recommendation for BHSS review, and initiate preparation for IRB review and approval at the level in which the study qualifies
   D. When the RCA finalizes the meeting agenda, the IRB database will automatically send copies of the agenda directly to the IBSO for review.
   E. If during the BHSS review process new information is identified that alters the risk/benefit ratio for participants, requires a change in the consent form, or alters the proposal, the Investigator in the form of an amendment must submit this new information to the IRB.
F. Appropriate database entries will be completed.