Procedure for Obtaining Institutional Biosafety Committee (IBC) Approval

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

I. Investigator Responsibilities.
   A. When conducting research involving humans, the Investigator will contact the IBC when the proposed research involves:
      1. Experiments involving the deliberate transfer of recombinant DNA or RNA or DNA or RNA derived from recombinant DNA 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;
      3. Any research activity utilizing a "Select Agent" as defined by the CDC in 42 CFR 72 Appendix A must be approved by the IBC before final IRB approval may be granted. The "Select Agent" list may be found on the CDC website at http://www.cdc.gov/od/sap/42cfr72.htm#Appendix%20A.
      4. Investigators utilizing recombinant DNA or potentially infectious microorganisms in the course of his or her research, but not for direct and deliberate transfer into human participants. However, IBC final approval under these circumstances is not required prior to IRB approval.

   B. The Investigator will submit a "Registration Application for Research with Recombinant DNA Molecules and/or Infectious Agents" to the Institutional Biological Safety Officer (IBSO). Biosafety instructions and forms are located on the Biosafety website located at http://www.safety.vanderbilt.edu/resources/biosafety.htm.

   C. The Investigator will forward any new information identified during IBC 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 (See HRPP Policy III.J). This amendment must also be sent to the IBC for review and approval.

II. IRB Committee Responsibilities.
   A. The IRB Committee will assure that all human research requiring IBC approval has been submitted to the IBC for review and approval prior to granting final IRB approval.
   B. The IRB Committee, IRB Chair, or designated Committee Member may consult with the IBSO for guidance as needed.
   C. The IRB will review studies, in which IBC approval is also required, per HRPP policies and procedures, federal guidelines and regulations.

III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.
   A. The RCA will screen IRB submissions during the pre-review process to determine if IBC approval is not required or has been initiated or granted.
   B. In the event that the RCA questions the need for IBC approval, he or she should contact the IBSO.
   C. The RCA will place the new study on the next available agenda regardless of the need for IBC approval, and initiate preparation for IRB review and approval at the level in which the study qualifies.
D. When the RCA finalizes the meeting agenda, copies of the agenda are sent directly to the IBSO for review.

E. A study requiring IBC approval may receive an IRB Committee recommendation of approved pending. However, prior to final approval being granted, the RCA will consult HRPP Policy VI.C to assure that the study may be granted final IRB approval prior to receiving IBC approval. If the study requires IBC approval prior to granting final IRB approval, the RCA will contact the IBSO for a status update. Further, if during the IBC approval 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.