Subject: IRB Committee’s Relation to Other University Committees and External Reviews

Definitions:

1. Biologicals and Human Subjects Subcommittee (BHSS): A Committee which provides oversight of Human Gene Transfer, the deliberate transfer of DNA, transfer of DNA or RNA derived from recombinant DNA into human research participants.

2. Human Subjects Radiation Committee (HSRC): A sub-committee, under the Vanderbilt University IRB, which is responsible for the review and approval of research protocols involving human participants and radiation exposure.

3. Institutional Biosafety Committee (IBC): 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 also provides guidance on the proper acquisition, handling, transfer, and disposal of potentially hazardous or regulated biological materials.

4. Radioactive Drug Research Committee (RDRC): A sub-committee, under the Vanderbilt University IRB, which is responsible for the review and approval of research protocols involving human research participants and radioactive drug exposure.

5. Vanderbilt Institute for Clinical and Translational Research Scientific Review Committee (VICR SRC): A Committee required by Vanderbilt's Clinical and Translational Science Award (CTSA). Review is required for all Investigators who propose the use of VICTR funding for research activities associated with an individual protocol. The Committee reviews to assure scientific merit and research design including statistical soundness as well as to determine if the research proposed aligns with the overall Institute's goals and mission.

6. Vanderbilt-Ingram Cancer Center's Scientific Review Committee (VICC SRC): A Committee required by the Vanderbilt-Ingram Cancer Center's Support Grant from the NCI to review all proposed research related to cancer. The Committee reviews to assure scientific merit and research design including statistical soundness as well as determining if the research proposed aligns with the overall Cancer Center's goals and mission.

Policy:

It is the policy of the Human Research Protections Program (HRPP) to work in coordination with other Committees and external review resources to provide protections to research participants.

I. The IRB functions independently, but in coordination with other VU and VUMC Committees

II. Institutional Biosafety Committee (IBC). The following types of research must receive IBC review and approval

   A. Any research activity involving the deliberate transfer of recombinant DNA or RNA or DNA or RNA derived from recombinant DNA into one or more human research participants must be approved by the IBC before final IRB approval may be granted.

   B. Any research activity utilizing investigational, live, recombinant, and/or attenuated microorganisms for the purposes of vaccination or infection of one or more human research participants must be approved by the IBC before final IRB approval may be granted.

   C. Any research activity utilizing a “Select Agent” as defined by the CDC in 42...
IV. Radioactive Drug Research Committee (RDRC).
A. The RDRC is authorized by the U.S. Food and Drug Administration (FDA) to approve research projects which involve the use of certain non-approved radioactive drugs for pre-Phase I research. Use of these drugs would otherwise require the approval of the FDA in the form of an IND. In order to qualify for this in-house approval, the study must satisfy the following criteria:
1. The research project must be intended to obtain basic information regarding human physiology, pathophysiology, or biochemistry, or basic information regarding the metabolism of a radioactively labeled drug. The project must not be one intended to determine safety and effectiveness of a drug (i.e., to carry out a clinical trial) or one intended primarily for immediate diagnostic or therapeutic purposes.
2. The radioactive drug must be pharmacologically inactive. For an interpretation, see item III in the Guidelines for Completing RDRC Application Forms available on the HRPP web site.
3. As described in 21 CFR § 361.1, strict radiation dose limits must be met, in order to ensure that the subject receives the smallest radiation dose with which it is practical to perform the study without jeopardizing the benefits to be obtained from the study.
4. The study must meet other requirements set forth in the Guidelines regarding qualifications of Investigators use of minors as research subjects, etc. It is important that Investigators refer to the guidelines to determine if all of the criteria are satisfied. If all criteria are not satisfied, the study cannot be approved by the RDRC but must be conducted under an IND.

B. IRB applications requiring approval from the RDRC received in the IRB office prior to approval by the RDRC will be routed by the IRB to the RDRC. Applications must receive this approval prior to review by any of the IRB Committees. This is necessary to assess the level of risk to human participants as required by federal regulations (See HRPP Policies and Procedures Section XII).

V. Medical Center Conflicts of Interest Committee (MCCOIC) or University Conflicts Committee (UCC) Approval.
A. Any actual or perceived conflicts of interest as defined by Institutional policy must be reported to and reviewed by the MCCOIC or the UCC whichever is applicable.
B. The IRB Committee may not grant IRB final approval of projects with a disclosed conflict of interest unless final approval has been granted by the MCCOIC/UCC and the appropriate template language regarding conflict of interest has been included into the informed consent documents and all
additional recommendations made by the MCCOIC or UCC have been incorporated into the informed consent documents and research plan.

C. Should the MCCOIC or UCC make recommendations for change to the Investigator’s approved research application, protocol, or informed consent documents, the Investigator will submit the revised documents as an amendment using the “Request for Amendment”.

VI. Other Committee Approvals Not Required Prior to IRB Approval. At times, research may be subject to review and approval of other University Committees (e.g., VICTR SRC, VICC SRC, etc.) or External Review Committees (e.g., Research Cooperative Group). The IRB application will include the documentation of the need for these required approvals. In addition, the IRB will document in the Final Approval Letter (FAL) that IRB approval has been granted but it is the Investigator’s responsibility to obtain approval from any other required committee and receive IRB approval of any changes required by these other Committees to the existing application before initiating the research.

A. VICTR SRC approval is posted on the web-based portal (StarBRITE) once final approval has been issued and is available to the investigator, key study personnel and the HRPP.

B. A copy of all VICC SRC communications to the Investigator from the Committee are forwarded to the IRB when issued to the Investigator.

VII. External Consultant Review. Any IRB Committee may refer IRB applications for review by an external consultant if the IRB Committee determines an expert opinion is needed or is unable to determine the risks and benefits of the research or the specific aims or design of the research.

References:
42 CFR 72
45 CFR 46
21 CFR 361.1
HRPP Policy XII.A