Subject: Institutional Oversight of Assurance

Definitions:
1. **Assurance**: A contract or agreement that establishes standards for human subjects research as approved by the Office for Human Research Protections (OHRP) also known as a Federalwide Assurance (FWA).
2. **Department of Health and Human Services (DHHS)**: The United States government's agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves.
3. **Institutional Biosafety Committee for Human Subjects (IBC-HS)**: 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 or research utilizing investigational, live, recombinant, and/or attenuated microorganisms for the purposes of vaccination or infection into a human.
4. **Institutional Review Board (IRB)**: A specifically constituted review body established or designated by an entity to protect the rights and welfare of human subjects recruited to participate in biomedical or behavioral/social science research.
5. **IRB of Record**: An IRB is considered the IRB of record when it assumes IRB responsibilities for another institution or legal entity and is designated to do so through an approved Assurance with OHRP. A Memorandum of Understanding is required, designating the relationship, for VU to serve as the IRB of Record.
6. **Memorandum of Understanding (MOU)**: A formal agreement between VUMC and another institution that identifies the VUMC Institutional Review Board as the IRB of record for that institution, also known as a Reliance Agreement.
7. **Office for Human Research Protections (OHRP)**: The office under the Department of Health and Human Services responsible for implementing DHHS regulations (45 CFR 46) governing biomedical and behavioral/social science research involving human subjects.
8. **Radioactive Drug Research Committee**: A sub-committee, under the Vanderbilt University Institutional Review Board, which is responsible for the review and approval of research protocols involving human participants and the administration or use of radioactive drugs.
9. **Vanderbilt Institutional Human Pluripotent Cell Research Oversight Committee (VIHPCRO)**: A sub-committee, under the IRPP responsible for oversight of all pluripotent cell and fetal tissue use in research.

Policy:
It is the policy of the Vanderbilt University Human Research Protections Program through its IRBs to uphold its Assurances as filed with the Office for Human Research Protections (OHRP).

I. A full copy of both Vanderbilt University and Vanderbilt University Medical Center’s Assurances will be maintained in the office of the HRPP Director, and will be available to the VU and VUMC community via the VU HRPP website. The Assurances are based on the following principles:
A. Safeguarding the rights and welfare of human participants in research and other research activities is a general Institutional policy delegated by the Chancellor through the Executive Vice President for Research and the Vice Provost for Research. It is their responsibility to exercise appropriate administrative oversight to assure that the HRPP’s policies and procedures designed for protecting the rights and welfare of human participants are effectively applied in compliance with its Assurances.

B. The Executive Vice President for Research and the Vice Provost for Research may designate an individual with sufficient knowledge and standing as the Human Research Protection Program (HRPP) Institutional Official (IO). This individual is responsible for assuring that the HRPP functions effectively and that the Institution is informed of the resources and support necessary to comply with all requirements applicable to research involving human subjects. VU and VUMC faculty, staff, and students, which comprise its schools, departments, divisions, and facilities, are subject to the Assurances and this policy. This includes any research for which an Assurance or another formal agreement (e.g., MOU) identifies the VUMC Institutional Review Board (IRB) as the IRB of record.

C. VU and VUMC agree to uphold the ethical principles of the Belmont Report to all research involving human participants. The ethical principles set forth in the Belmont Report are:
   1. Respect for Persons: Recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy;
   2. Beneficence: Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risk of harm; and

D. The HRPP will apply DHHS regulations (45 CFR 46, including Subparts A, B, C, and D) to all federally supported research involving human participants.

E. The HRPP further agrees to apply additional regulations such as, the U.S. Food and Drug Administration Human Subject Regulations (21 CFR 50, 56, 312 and 812), and the Health Insurance Portability and Accountability Act of 1996 (HIPAA), when applicable, to research involving human participants under review.

II. Structure of the Institutional Review Board.

A. The IRB Committees are appointed as Institutional Committees. As such, the IRB Committees serve VU and VUMC as a whole, rather than a particular school or department, and any institution for which the VUMC IRB is designated as the IRB of record in an Assurance filed with OHRP with a corresponding MOU.

B. The Assurances presently designate four (4) OHRP-registered IRB Committees. Designation of additional IRB Committees under the Assurance requires prior notification of and approval by OHRP.
   1. The three Committees for Health Sciences review studies designated primarily to increase the scientific base of information about normal or abnormal physiology and development, and studies primarily intended to evaluate the safety, efficacy, and usefulness of drugs, biologics, devices, medical products, procedures or interventions.
   2. The Committee for Behavioral and Social Sciences reviews studies designated to contribute to behavioral, educational, and social science research. Both quantitative and qualitative evaluations address issues of confidentiality, coercion, distress, and effects on social status.

III. Responsibilities of the IRB to Provide Oversight for its Assurance Agreements.

A. Approval of the IRB is required prior to the initiation of all humans in research.

B. Through the review process, the IRB has the authority to approve, require modifications, suspend, disapprove, or terminate all research activities that fall within its jurisdiction.

C. Research reviewed and approved by the IRB may be subject to review and disapproval.
by officials of Vanderbilt University, Vanderbilt University Medical Center, or any institution for which the VUMC IRB is designated as the IRB of record in accordance with an Assurance or a signed MOU with the VUMC IRB.

D. However, officials may not approve research that has not been approved by the VUMC IRB.

E. The IRB is also responsible for the operational support, initial and ongoing training, and oversight of the Radioactive Drug Research Committee (RDRC), the Institutional Biosafety Committee for Human Subjects (IBC-HS), and the Vanderbilt Institutional Human Pluripotent Cell Research Oversight Committee (VIHPCRO).

References:
The Belmont Report 45 CFR 46
21 CFR 50 and 56, 312, 812
45 CFR 160 and 162
HRPP I.A.1 - Procedure for Institutional Oversight of Assurance