Subject: Activities Subject to IRB Jurisdiction

Definitions:

1. **Agent**: An individual employed by VU or VUMC who is authorized to act on its behalf.
2. **Clinical Investigation**: Any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505 (i) or 520 (g) of the Federal Food, Drug and Cosmetic Act, or need not meet the requirements for prior submission to the FDA under these sections of the Federal Food, Drug and Cosmetic Act, but the results of which are intended to be later submitted to, or held for inspection by the FDA as a part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are synonymous for purposes of FDA regulation.
3. **Food and Drug Administration**: The office responsible for implementing regulations governing the use of investigational drugs, biologics, devices and radiological procedures including radioactive drugs in clinical investigations with humans.
4. **Generalizable Knowledge**: The HRPP defines this as information that is gathered by a research protocol or project that answers a research question (i.e., hypothesis). Resultant information should be able to be applied to the general population relative to the population targeted.
5. **Human Subject**: A living individual about whom an Investigator (whether professional or student) conducting research obtains data through intervention or interaction with an individual or with his/her identifiable private information or an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject might be either a healthy individual or a patient. For research involving medical devices a human subject is also an individual on whose specimen an investigational device is used. When medical device research involves in vitro diagnostics and unidentified tissue specimens, the FDA defines the unidentified tissue specimens as human subjects.
   a. **Intervention**: Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subjects’ environment that are performed for research purposes.
   b. **Interaction**: Includes communication or interpersonal contact with a subject or their private identifiable information.
   c. **Private Information**: Includes information about behavior that occurs in a setting in which an individual can reasonably expect that no observation or recording is taking place. It includes information, which has been provided for specific purposes by an individual, and the individual can reasonably expect will not be made public (e.g., a medical record). Private information must be individually identifiable in order to be considered information to constitute research involving human subjects. This may include identifiable private information obtained from a primary subject about a third party.
   d. **Test article**: Any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to FDA regulation.
6. **Memorandum of Understanding (MOU)**: A formal agreement between Vanderbilt University and another institution that identifies the Vanderbilt University Institutional Review Board as the IRB of record for that institution.
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. **Research:** Any systematic investigation (including research development, testing and evaluation) designed to develop or contribute to generalizable knowledge.

9. **Human Subjects Research:** Any research that involves humans as subjects and any clinical investigation.

10. **Systematic Investigation:** Any activity that involves a prospective study plan including research development, testing, evaluation and data collection to answer a study question or hypothesis.

**Policy:**

It is the policy of the Human Research Protections Program to have jurisdiction over all human subjects research subject to its Assurances.

I. **Review and Approval of Human Subjects Research.**

A. All human subjects research, and all other activities, which in part involve human subject research, regardless of sponsorship, must be reviewed and approved by the VUMC IRB.

   1. No intervention or interaction with human subjects in research, including advertising, recruitment, and/or screening, may begin until the IRB has reviewed and approved the research.

   2. It is the responsibility of the IRB Chairperson or his/her designee or the full IRB Committee to determine what activities constitute as “human subjects research.”

B. The Assurances with the federal government define jurisdiction over the review of human subjects research. Regardless of sponsorship, the IRB must review all human subjects research if one or more of the following apply:

   1. The research is sponsored by VU or VUMC;

   2. The research is conducted by or under the direction of any employee, faculty, staff, student, or agent of VU or VUMC in connection with his/her institutional responsibilities;

   3. The research is conducted by or under the direction of any employee or agent of this institution using any of its property or facilities;

   4. The research involves the use of non-public information maintained by VU or VUMC to identify or contact human subjects or prospective subjects;

   5. VU or VUMC receives a direct federal award to conduct human subject research, even where all activities involving human subjects are carried out by a subcontractor or collaborator; and/or

   6. The research is conducted in accordance with Assurances filed with the Office of Human Research Protections (OHRP) in which the VUMC IRB is designated as the IRB of record through an established Memorandum of Understanding.

C. If an Investigator begins a non-research project and later finds that the data gathered could contribute to generalizable knowledge, the Investigator must submit a proposal to the IRB for review and approval prior to publication or presentation of the data (e.g., journal article, poster session, public speech or presentation, or project report).

II. **Failure to Submit a Project for IRB Review.**

A. The implications of engaging in activities that qualify as research that is subject to IRB review without obtaining such review are significant. Results from such studies may not be published or presented unless IRB approval had been obtained prior to collecting the data. To do so is in violation of HRPP Policy. It is also against policy to use that data to satisfy thesis or dissertation requirements.

B. Investigators who request approval to continue human subjects research that was not previously reviewed or to use data that was collected without IRB approval face the possibility that the IRB will administratively withdraw or request the PI administratively withdraw his/her application, as the IRB cannot give post-hoc approval.

C. The IRB may not approve applications where the Investigator has attempted to
circumvent IRB policies and procedures regarding human subjects research by collecting data as non-research and then applying to use them as existing data. It is therefore in the Investigator's best interest to consider carefully the likelihood that he or she will want to use the data for research purposes in the future, and to err on the side of inclusion and seek IRB approval prior to commencing the work.

References:
45 CFR 46
21 CFR 50 and 56