Subject: Investigator Qualifications

Definitions:

1. Assurance: A contract or agreement that establishes standards for human research as approved by the Office for Human Research Protections (OHRP).

2. 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.

Policy:
It is the policy of the Human Research Protections Program (HRPP) that all Investigators meet the following requirements to conduct human subjects research under the jurisdiction of the HRPP and IRB.

I. As described in HRPP Policy I.A, VU and VUMC’s Federalwide Assurances (FWA) with the federal government specifies that all human subjects research that is conducted by or under the direction of any employee, faculty, staff, student, or agent of VU or VUMC in connection with his or her institutional responsibilities must be reviewed by the IRB.

II. All Vanderbilt employees, faculty, staff, students or agents of Vanderbilt University or Vanderbilt University Medical Center will have reviewed the ethical principles of The Belmont Report, federal and state laws and regulations, institutional policies and procedures, HRPP policies and procedures, and if applicable, Good Clinical Practice standards when conducting human subjects research. Additionally, they will have completed the required training (initial and continuing education) for the ethical conduct of human subjects research (See HRPP Policy VIII.A).

III. Student Conducted Research. As stipulated in HRPP Policy I.B, all activities that meet the definition of research with human subjects and that are conducted by students must be reviewed by the IRB.

A. Activities that must be reviewed and approved by the IRB include:
   1. All master’s theses and doctoral dissertations that involve human research participant; and
   2. All class or other projects that involve human research participants and for which findings may be published or otherwise disseminated and contribute to generalizable knowledge.

B. Oversight by Faculty Advisor. All students and fellows applying for IRB review must obtain the signature of their faculty advisor on the Signature Page of their application. The faculty advisor must have completed the required training for the ethical conduct of human subjects research and accepts responsibility for the oversight of the student-conducted research.
IV. **Conflict of Interest.** The protection of human research participants requires objectivity in communicating risks, selecting subjects, promoting informed consent, and gathering, analyzing and reporting data. Therefore, the IRB should consider conflict of interest issues in its deliberations of applications (See HRPP Policy VI.C).

V. All individuals conducting human subjects research must be adequately qualified and licensed relevant to the scope and complexity of the research conducted.

**References:**
HRPP Policy I.A
HRPP Policy I.B
HRPP Policy VI.C