GUIDANCE: MEANING OF DEPARTMENTAL SIGNATURE ON THE SIGNATURE ASSURANCE SHEET

Research involving investigation and/or collection of data from living human subjects requires review by the IRB prior to initiation of a study. The IRB focuses its principal attention on human subjects protections when evaluating a research proposal which involves consideration of scientific validity, investigator qualifications, subject population, facilities, and mentoring in relation to participant risk. The IRB wishes to assume that research conducted as part of the University’s mission is designed and carried out in a manner that meets the highest scientific standards and with a commitment to human subjects protections and hopes to minimize occasions on which it must question scientific aspects of studies. Therefore, the IRB requests that, in addition to investigators and faculty advisers, each department, school, or college designate a person to sign an Assurance Statement that protocols—whether exempt, expedited, or full-board reviewed and by students, faculty, or staff—meet these human protections guidelines. The exact mechanism by which it does this or by whom it is done is the department’s choice but each department should inform the IRB annually of its decision about designated signers. By reviewing the IRB application and signing the Assurance Statement, the signer assumes certain responsibilities and signifies that the science is meritorious and deserving of conduct in humans.

The following are the responsibilities reflected by signing the Assurance statement:

1. **Scientific validity.** The Signer has reviewed the application prior to IRB submission and attests that the science represented in the research protocol is valid and likely to achieve its aim and the knowledge to be gained has importance.

2. **Qualifications.** The Signer has ensured that the investigator(s) has sufficient time to conduct the research; is knowledgeable about the regulatory requirements of the sponsor (if research is sponsored) and can comply with them; that the study personnel have the necessary expertise and training for the work; and that there are sufficient staff to accomplish the task.

3. **Subject population.** The Signer has ensured that the investigator has access to a population that should allow recruitment of the required sample within the proposed recruitment period and that if participants need ancillary services as a consequence of taking part in the research (psychological counseling or emergency treatment), the investigator has a process to make these services available.

4. **Facilities.** The Signer has ensured that the facilities and equipment needed to conduct the research are adequate and appropriate.

5. **Mentoring.** The Signer has ensured that guidance to the investigator(s) during the study is available in order to assure adherence to established standards of scientific integrity.