

Institutional Statement of Commitment To the Protection of Human Research Participants

Guiding Principles

All research activities involving human participants at the University of Oklahoma is guided by the ethical principles set forth in “The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research,” the Declaration of Helsinki and the Nuremberg Code. In addition, the University of Oklahoma adheres to the Office for Human Research Protection (OHRP) requirements, as set forth in 45 CFR 46 and its subparts A, B, C, and D, and the FDA in 21 CFR 50 and 56.

This basic commitment to the protection of human participants applies to all University of Oklahoma research projects involving human participants regardless of the source of funding or the location of the research.

Office of Human Research Participant Protection

The University of Oklahoma “OU” has established the Office of Human Research Participant Protection (HRPP) on the Norman and Oklahoma City campuses to support its commitment to the protection of human participants in research. The Oklahoma City campus HRPP office has established a satellite office at the Schusterman Campus in Tulsa. The Norman and Oklahoma City campus HRPP encompass Institutional Review Boards functioning in an autonomous manner to apply all federal regulations and ethical principles to OU research involving humans, regardless of sponsorship or performance site location.

The Institutional Review Boards (IRBs) are appointed as University Committees. As such, the IRBs serve OU as a whole, rather than a particular college or department, and any institution for which the University of Oklahoma is designated as the IRB of record in an Assurance filed with OHRP.

All research activities involving human participants must be reviewed and approved by one of the appropriate IRBs. Intervention or interaction with human participants in research, including recruitment, may only begin when the IRB has reviewed and approved the research project.

Institutional Roles

1. The Senior Vice President and Provost for each campus, as designated on the OU’s Federalwide Assurance, serve as the Institutional Officials. As such, the Senior Vice Presidents and Provosts, in consultation with the Director of Compliance and the appropriate Vice Presidents, have final oversight over the HRPPs. It is the responsibility of the Senior Vice President and Provost of each

campus to provide resources to the HRPPs so that the functions of the HRPP can be sufficiently executed. The Senior Vice President and Provost for each campus and the Director of Compliance are jointly responsible for providing an environment for the IRBs free of coercion, from investigators, sponsors, and the University.

2. The role and responsibility of the IRB is to protect the rights and welfare of human participants involved in research. The IRB has the authority to review and require modification to research or research-related activities, in conjunction with other Institutional committees such as Radiation Safety or Biosafety if applicable. If concurrent review of the research is required per Institutional policy, then all committees involved must provide affirmative support before final IRB approval is granted. However, the ability to approve or disapprove research or research-related activities lies solely with the IRB. IRB disapproval is binding and cannot be overturned by any Institutional committee or official. An Institutional committee or official may not approve the research if it has not been approved by the IRB.

In addition to the above review of research, 45 CFR 46.109 also endows the IRB with the authority to:

- Require all elements of informed consent, as outlined in 45 CFR 46.116, including those optional elements deemed beneficial to the protection of the rights and welfare of participants.
 - Require documentation of informed consent, unless the requirement for documentation has been waived in accordance with 45 CFR 46.117.
 - Provide notification to Investigators of favorable or unfavorable review of the research. In the event the review is unfavorable, the Investigator may be given the opportunity to respond in writing and in person.
 - Require continuing review of approved research activities at intervals appropriate to the level of risk, but at least once every year.
 - Observe, or have a third party observe, the consent process and conduct research audits.
 - Suspend or terminate approval of research activities that are not in accord with Institutional or Federal requirements, with notification to the Investigator, Institutional officials and Federal regulators.
3. University faculty, staff or students engaged in human participant research (as defined by HRPP) must receive prior approval, or notice of exempt status, from the IRB before initiation of any research activity, including participant recruitment. Investigators must allocate adequate resources to ensure the protection of human research participants.