

STATEMENT OF AUTHORITY AND PURPOSE

1. Mission Statement

The mission of the University of Oklahoma's (University) Office of Human Research Participant Protection (HRPP) is to protect the rights, privacy, and welfare of all human participants in research projects conducted by University faculty, staff, and students or otherwise conducted under their oversight.

2. Human Research Participant Protection Plan

2.1 Governance and Leadership

- 2.1.1 Uphold the University's Federalwide Assurance of Compliance (FWA) with the Department of Health and Human Services (DHHS), Office of Human Research Protection (OHRP).
- 2.1.2 Improve the research infrastructure by providing a human research participant protection program through strong and effective leadership.
- 2.1.3 Ensure an effective regulatory review system by providing excellent support services to the IRB members who review research.
- 2.1.4 Ensure standard operating procedures are maintained for the University's adherence to established policies, ethical guidelines, and compliance with regulatory requirements.

2.2 Research Infrastructure

- 2.2.1 Provide effective support to University faculty, staff, students, and other individuals under IRB oversight involved in human research.
- 2.2.2 Promote open communication and foster an atmosphere of compliance with all of the University's organizational components.

2.3 Education and Quality Improvement

- 2.3.1 Maintain rigorous education and quality improvement programs in order to ensure all of the human research participant protection components are in compliance with the regulations, policies, and standard operating procedures.

2.4 Risk Assessment

- 2.4.1 Evaluate and assess risks for strengthening the human research participant protection program and initiate improvements.

3. The HRPP

The HRPP is the University's established program designed to support the University's commitment to the protection of human participants in research. The goals of this program are to provide safety for human participants in research, to educate the University's researchers, and to provide continuous quality improvement of the University's research activities.

4. Governing Principles

All of the University's Institutional Review Boards (IRBs) are guided by the ethical principles applied to all research involving humans as participants, as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, titled: Ethical Principles and Guidelines for the Protection of

Human Subjects of Research (the "Belmont Report"). These principles are defined in the Belmont Report (Appendix K) as follows:

Respect for Persons -- Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

Beneficence -- Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: **(1)** do not harm and **(2)** maximize possible benefits and minimize possible harms.

Justice -- The selection of participants is equitable and is representative of the group that will benefit from the research. Justice requires that the benefits and burdens of research be distributed fairly.

5. Applicable Laws

The IRB's purpose and responsibility is to protect the rights and welfare of human participants. The IRB reviews and oversees such research to require that it complies with federal regulations at 45 CFR 46, and its subparts A, B, C, D and E; the U.S. Food and Drug Administration 21 CFR 50, 56, 312, 314, 601, 812, and 814; Oklahoma law; and all other pertinent regulations and applicable guidelines.

The University agrees to apply additional regulations such as the Health Insurance and Portability and Accountability Act of 1996 (HIPAA) at 45 CFR 160 and 164, and the U.S. Department of Veterans Affairs regulations, 38 CFR 16, to research involving human participants under review when applicable.

The University agrees to apply 45 CFR 46, subpart A (the Common Rule) and the Department of Defense (DOD) Directive 3216.02 for the additional requirements when human participants research is conducted or supported by the DOD.

6. Organizational Components, Structure, Roles, and Responsibilities

6.1 Institutional Officials

- 6.1.1 The Senior Vice President and Provosts of the Norman Campus and Health Sciences Center Campus are the Institutional Officials, and they report to the University President.
- 6.1.2 The Senior Vice President and Provosts for each campus have signatory authority for the OHRP FWAs and FWA addendum when human participants research is conducted or supported by the DoD.
- 6.1.3 The Senior Vice President and Provosts for each campus are responsible for the conduct of human research of the Norman Campus and the Health Sciences Center Campus respectively. The Senior Vice President and

Provosts have been granted authority to provide for the appropriate allocation of funds, facilities, and employees necessary to operate the HRPP programs and to maintain and enforce the independent nature of the relationship between the IRB and the University.

- 6.1.4 For more information, see the HRPP/IRB organizational chart located on the OU Office of Compliance website.

6.2 Organizational Official

- 6.2.1 The Vice President of the University and General Counsel is the Organizational Official responsible for the Office of Human Research Participant Protection (HRPP), through the Director of Compliance. The Organizational Official reports to the President.
- 6.2.2 The Vice President of the University and General Counsel has the authority to oversee the HRPP and ensure its effectiveness in protecting research participants. The HRPP operates under the auspices of the Vice President of the University and General Counsel, but signatory authority for signing the OHRP FWAs lies with the Senior Vice President and Provost of each campus.
- 6.2.3 For more information, see the HRPP/IRB organizational chart and the Presidential Policy-Organizational Official for Human Research Protection Program, located on the OU Office of Compliance website.

6.3 Director of Compliance

- 6.3.1 The Board of Regents of the University of Oklahoma created the Office of Compliance to address adherence to federal, state, and institutional regulations regarding standards of conduct in research and other areas. The Office of Compliance promotes and fosters ethical integrity involving research and other activities. Through the Office of Compliance, the University coordinates resources to train HRPP staff, IRB members, investigators, and research staff in human participant protection, care, and safety.
- 6.3.2 The Director of Compliance has direct oversight of the Offices of HRPP and reports to the Vice President of the University and General Counsel.
- 6.3.3 The Director of Compliance is responsible for oversight of the operation of the Office of HRPP for each campus including staffing, budget, and performance of the HRPP.
- 6.3.4 The Director of Compliance maintains a Hot Line where individuals can anonymously report concerns or violations. The Director of Compliance can direct audits of areas of potential concern and reports the findings to the Senior Vice President and Provosts of the respective campuses and the Vice President and General Counsel.
- 6.3.5 The University established the Compliance Advisory Committee (CAC) composed of senior University administrators who meet regularly to review the status of the Compliance Program, including the Office of HRPP. The Director of Compliance reports the status of the program to the CAC.

6.4 Offices of Human Research Participant Protection

- 6.4.1 The Directors of the Offices of HRPP manage the Norman and Health Sciences Center Campus Offices of HRPP. The Directors of the HRPP report to the Director of Compliance.
- 6.4.2 The Directors of the Offices of HRPP are responsible for the day-to-day management and operations of the program. This responsibility includes managing the IRBs; upholding and maintenance of the FWA; and managing the Education Program, Quality Improvement Program, and Participant Outreach Program. The Education Program is designed to ensure that Investigators, key personnel, IRB members, and HRPP staff are knowledgeable in the applicable elements of the human research participant protection program. The Quality Improvement Program is designed to continually evaluate, provide education, and improve the research process, ultimately providing a higher degree of safety to human research participants. The Participant Outreach Program is designed to enhance the understanding of human research by participants or prospective participants, respond to concerns and questions about research from participants and the community, and conduct outreach and education activities with participants and the community.

6.5. Institutional Review Boards

- 6.5.1 The Directors of the Offices of HRPP manage the Norman and Health Sciences Center Campus IRBs. The IRBs, units within the HRPP, are established and empowered under the auspices of this University's executive authorities to review biomedical and behavioral research involving human participants. Although the IRBs function independently, their review can be coordinated with the requirements of other University offices and committees. There are two IRBs on the Norman Campus and five on the Health Sciences Center Campus.
- 6.5.2 The Directors of the Offices of HRPP are responsible for the day-to-day management and operations of the IRBs, including management of IRB staff, IRB membership, IRB membership rosters; maintenance of policies and standard operating procedures; and prompt reporting of 1) unanticipated problems involving risks to participants or others, 2) serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB(s), and 3) suspension or termination of IRB approval.
- 6.5.3 The IRBs have the responsibility to provide oversight for the research conducted under the University's FWA. The University requires that all research projects involving humans as participants or human material be reviewed and approved by an IRB prior to initiation of any research-related activities, including recruitment and screening activities. This responsibility includes training key personnel, processing applications to the IRBs, coordinating IRB meetings, and acting as a liaison between the investigators and the IRBs. The IRBs are responsible for documenting their findings regarding ethical considerations, scientific and scholarly merit, and adherence to applicable regulations and policies of research projects reviewed.

6.6 Offices of Research Services/Administration

- 6.6.1 The Office of Research Services (Norman Campus) and the Office of Research Administration (Health Sciences Center Campus) serve as central resources to faculty for all pre- and post-award administrative aspects for sponsored research, training, and service activities.
- 6.6.2 The Office of Research Services (Norman Campus) and the Office of Research Administration (Health Sciences Center Campus) are responsible for negotiating sponsored and non-sponsored agreements, including but not limited to clinical trial, confidentiality, material transfer, and professional service agreements and subcontracts. These offices serve as the University's liaisons with external funding agencies for all pre- and post-award administrative matters.

6.7 Investigators

- 6.7.1 Investigators perform their work under the direct supervision of the department chairs, who report to the Senior Vice President and Provost of the respective campuses.
- 6.7.2 Investigators are responsible for conducting research in such a manner as to guard the safety of participants and to be compliant with all applicable regulations and policies.
- 6.7.3 Investigators shall ensure that study personnel are adequately trained and are responsible for complying with all applicable regulations and human research participant protection policies.
- 6.7.4 It is the Investigator's responsibility to keep the IRB informed of all problems for which the IRB requires prompt reporting.

7. Interactions of Organizational Components

- 7.1 The successful fulfillment of the University's organizational components to protect participants requires open communication among the components. As such, regular reports, meetings, and other forms of communication are used both horizontally and vertically within the groups and individuals participating in the human research participant protection program.
- 7.2 The University's organizational policies relating to the conduct of human research are coordinated through the Office of Compliance. The Office of Research Administration (Health Sciences Center Campus) or the Office of Research Services (Norman Campus) coordinate and administer the University's standards with sponsors. The Office of HRPP coordinates and administers the University's standards for research participants.
- 7.3 The University is comprised of multiple review committees for proposed research, depending upon the type of research. As such, there are multiple lines of communication between the IRB and the other review committees, as well as between the Norman and OUHSC Offices of HRPP and representatives of the IRBs.

8. Commencement of Research

The University components work together to ensure that research does not commence until all required approvals are obtained. All research activities involving human participants must be reviewed and approved by one of the appropriate IRBs. Research may not commence until all committees and offices have completed their review and provided documentation to the IRB. The IRB will withhold the study approval letter until all applicable documentation is received and applicable agreements with industry sponsors have been signed.

9. Conditions Under Which Activities Become Subject to HRPP

9.1 When an Activity is Research

9.1.1 The University becomes engaged in human participant research when its employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(d),(f)]. Agents are defined by the University as individuals performing institutionally-designated activities or exercising institutionally-delegated authority or responsibility. The University is automatically considered to be "engaged" in human participant research whenever it receives a direct HHS award to support such research.

9.1.2 Except for research in which the only involvement of humans is in one or more of the categories exempted or waived under 45 CFR 46 Section 101(b) (1-6) or 101(i), all research involving human participants and all other activities that involve such research, even in part, regardless of sponsorship, are subject to IRB review if one or more of the following apply:

- The research is sponsored by the University; or
- The research is conducted by or under the direction of any employee, faculty, staff, student, or agent of the University in connection with his or her institutional responsibilities; or
- The research is conducted by or under the direction of any employee, faculty, staff, student, or agent of the University using any of its properties or facilities; or
- The research involves the use of the University's non-public information to identify or contact human research participants or prospective participants; or
- The research is conducted by or under the direction of an individual employed by any affiliated sites and who is performing the research at that site.

9.2 When Research is Subject to HRPP

University policy states that all research involving human participants, as defined in 45 CFR 46 Section 102 (f) and the glossary term, even if it may be exempt from IRB review per 45 CFR 46 Section 101(b)(1-6) or 101(i), must be reviewed by an IRB or its designee before research activities commence, to ensure that participants and/or participant interests are appropriately protected.

According to federal regulations, the activities that require IRB review include any activities involving the collection of data through intervention or interaction with a living individual or involving identifiable private information regarding a living individual.

Specific activities that require IRB review include, but are not necessarily limited to, the following:

- Any experiment that involves a test article and one or more human subjects, and that 1) meets the requirements for prior submission to the Food and Drug Administration (FDA) under relevant investigational drug or medical device provisions of the Food, Drug, and Cosmetic Act, or 2) do not meet the requirements for prior submission to the FDA, but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit.
- A patient's care or assignment to intervention is altered for research purposes in any way.
- A diagnostic procedure for research purposes that is added to a standard treatment.
- Systematic investigation involving innovative procedures of treatments, for example, if a physician plans to collect information about the innovation for scientific purposes or will repeat the innovation in other patients in order to compare it to standard treatment.
- Emergency use of an investigational drug or medical device. The patient in such case is a research subject as defined by FDA regulations, and FDA requires that data generated from the care be used in reports of the research activity to FDA. However, in order to meet the FDA exemption from prior IRB review, the activity cannot be a prospectively planned systematic investigation designed to develop or contribute to generalizable knowledge.
- Human cell or tissue (genetic tissue) research collection, storage, and distribution of human tissue materials for research purpose when that activity meets the definition of human participants research per 45 CFR 46, Section 102 (f) and the glossary. IRB review is not required if the activity does not meet the definition of human participants research.
- Investigator-initiated research, where an Investigator both initiates and conducts, alone or with others, a clinical trial. In the case of Investigator-initiated studies, it is the Investigator's responsibility to keep the IRB informed of unanticipated non-serious research-related events and unanticipated serious adverse events and other unexpected findings that affect the risk/benefit assessment of the research, even if the event occurred at a location for which the Institution's IRB is not the IRB of record. The IRB recommends an independent data safety monitoring board (DSMB) review all reportable adverse events; the DSMB reports are forwarded to the IRB in addition to individual reports.
- Student-conducted research that meets the definition of research with human participants and is conducted as a degree requirement must be reviewed by the IRB. This includes all research with human participants that: (i) is conducted to meet master's theses and doctoral dissertations research requirements; and (ii)

is conducted with the intent to publish or otherwise disseminate research findings.

- Three or more case studies qualify as a research project at the University, such as when a series of participant observations are compiled in such a way as to allow possible extrapolation or generalization of the results from the reported cases. Such activity constitutes research that must be reviewed by the IRB. Additionally, this type of activity must always be reviewed by the IRB when there is intent to publish or disseminate the data or findings. Publication of one case study that will include the addition of a procedure that is outside of standard of care qualifies as research and must be reviewed by the IRB.
- Research that is not medically invasive, not clinical, and not health-related but does involve human participants also is required to go through IRB review. The definition of research with human participants includes: *"A systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge that involves a living individual about whom an investigator, (whether professional or student) obtains data through an interaction with the individual or obtains identifiable private information."* The intention to contribute to such knowledge is key to the definition, whether or not the completed research does make such a contribution or is accepted for publication. All of the following activities may meet the definition: Pilot studies (research development); Interview procedures; Surveys; Observations; Case studies; Oral histories; Analyses of existing data.
- Social/behavioral research that involves direct/indirect participant observation, questionnaires or surveys, interviewing, audiotaping, videotaping or photography, or review and analysis of existing data must be reviewed by the IRB. The IRB will consider the methods used in the study, storage, and destruction of data.

APPROVED BY: _____ **DATE:** 01/15/2010

NEXT ESTABLISHED REVIEW DATE: MAY 2012