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, students and those who conduct human research projects under the auspices of the University or otherwise under its oversight.

2. Human Research Participant Protection Plan

2.1 Governance and Leadership

2.1.1 Uphold the University’s Federalwide Assurance for the Protection of Human Subjects (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 SOPs 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 University oversight involved in human research.

2.2.2 Promote open communication and foster an atmosphere of compliance with all of the University’s components.

2.3 Education and Quality Improvement

Maintain rigorous education and quality improvement programs in order to ensure all of the human research participant protection components are in compliance with the applicable regulations, University policies, and SOPs.

2.4 Risk Assessment

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 for the safety of human participants in research, to educate the University’s investigators, 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 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**

Each IRB's purpose and responsibility are to protect the rights and welfare of human participants. The IRBs review and oversee such research to ensure that the research 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 will apply the Federal Policy for the Protection of Human Subjects (the Common Rule) to all human subject research, regardless of the source of funding, except where specified otherwise in the HRPP SOPs policies.

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 the Department of Defense (DOD) Directive 3216.02 as additional requirements when human participant 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 or their designees are the Institutional Officials. They report to the University President.

6.1.2 The Senior Vice President and Provosts or their designees have signatory authority for the OHRP FWAs and FWA addenda when human participant research is conducted or supported by the DoD on their respective campuses.
6.1.3 The Senior Vice President and Provosts or their designees are responsible for the conduct of human research of their respective campuses. The Senior Vice President and Provosts or their designees 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 of the IRB within the University.

6.1.4 For more information about the organizational structure, see the HRPP/IRB organizational chart located on the University 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, and is obligated to promote and foster ethical integrity involving research and other activities. 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 or designee for each campus.

6.2.3 For more information about the Organizational Official, see the HRPP/IRB organizational chart and the Presidential Policy-Organizational Official for Human Research Protection Program, located on the University 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 Norman Campus Office of HRPP and reports to the Vice President of the University and General Counsel. The Director of Compliance is responsible for oversight of the operation of the Office of HRPP for Norman Campus including staffing, budget, and performance of the HRPP.

6.3.3 The Director of Compliance maintains a Hot Line where individuals can anonymously report compliance-related 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 Provost or designees for the respective campuses and to the Vice President and General Counsel.

6.3.4 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.

6.3.5 The Director of Compliance reports the status of the HRPP to the CAC.

### 6.4 Health Sciences Center Vice President of Research

6.4.1 Through the Vice President for Research, the University coordinates resources to train
HSC HRPP staff, IRB members, investigators, and research staff in human participant protection, care, and safety.

6.4.2 The Vice President for Research has direct oversight of the HSC Office of HRPP and reports to the Senior Vice President and Provost. The Vice President for Research is responsible for oversight of the operation of the HSC HRPP including staffing, budget, and performance of the HSC HRPP.

6.5 Offices of Human Research Participant Protection

6.5.1 The Directors of the Offices of HRPP manage the Norman and Health Sciences Center Campus Offices of HRPP.

6.5.2 The Norman Campus HRPP Director reports to the Director of Compliance, and the HSC HRPP Director reports to the HSC Vice President for Research. The Directors of the Offices of HRPP are responsible for the day-to-day management and operations of the respective program. This responsibility includes managing the IRBs; upholding and maintaining 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.

6.6 Institutional Review Boards

6.6.1 The Directors of the Offices of HRPP manage the Norman and Health Sciences Center Campus IRBs, respectively. 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 submissions involving human participants and make a determination to approve, contingently approve, defer, or deny research submissions, as well as to suspend or terminate any approved research.

Although the IRBs function independently, their review can be coordinated with the requirements of other University offices and committees, such as those mentioned in section 602 of the SOPs. There are two IRBs on the Norman Campus and five on the Health Sciences Center Campus.

6.6.2 The Directors of the Offices of HRPP are responsible for the day-to-day management and operations of their respective IRBs, including management of IRB staff, IRB membership, and IRB membership rosters; maintenance of policies and SOPs; 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.

6.6.3 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 that are conducted by University faculty, staff, and students, as well as those conducted under its authority as described in Section 9.1.2 below 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 submissions 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.

6.7 Offices of Research Services/Administration

6.7.1 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.

6.7.2 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, 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.

6.8 Investigators

6.8.1 Investigators perform their work under the direct supervision of the department chairs, who report to the Senior Vice President and Provost or designee for the respective campuses.

6.8.2 Investigators are responsible for conducting research in such a manner as to guard the safety of participants and to be compliant with all applicable laws, regulations, ethical principles and guidelines.

6.8.3 Investigators shall ensure that key study personnel are adequately trained and for complying with all applicable regulations and human research participant protection policies.

6.8.4 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, meetings and other forms of communication are used both horizontally and vertically within the groups and individuals participating in the HRPP.

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) and the Office of Research Services (Norman Campus) coordinate and administer the University’s policies and SOPs 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 HSC Offices of HRPP and representatives of the IRBs.

7.4 The University does not allow any organizational components to approve human participant
research or authorize the initiation of human research activities unless the activities have already been approved by the IRB.

7.5 The University maintains the authority, through its administration, to disallow the conduct of IRB-approved research activities at the University or by University employees.

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.

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\(^1\) (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes [45 CFR 46.102(e), (l)]. 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 104, 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:

A. The research is sponsored by the University; or
B. 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 University responsibilities; or
C. The research is conducted by or under the direction of any employee, faculty, staff, student, or agent of the University using any of the University’s properties or facilities; or
D. The research involves the use of the University’s non-public information to identify or contact human research participants or prospective participants; or
E. The research is conducted by or under the direction of an individual employed by any affiliated site who is performing the research at that site.

9.2 When Research is Subject to HRPP

9.2.1 University policy states that all research involving human participants, as defined in 45 CFR 46 Section 102 (e) and the glossary term, even if it may be exempt from IRB review per 45 CFR 46 Section 104, must be reviewed by an IRB or IRB designee before research activities commence, to ensure that participants and/or participant interests are appropriately protected.

9.2.2 The definition of research with human participants includes: "A systematic investigation,

\(^1\) Agents are defined by the University as individuals performing institutionally-designated activities or exercising institutionally-delegated authority or responsibility.
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 information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. 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.

9.2.3 According to federal regulations, the activities that require IRB review include any activities involving research with human participants (as defined in 9.2.2).

9.2.4 Examples of activities that are considered human participant research and require IRB review are described on the HRPP website.

APPROVED BY: ________________________________ DATE: 09/03/2019

NEXT ESTABLISHED REVIEW DATE: AUGUST 2020