

Oklahoma State University Policy and Procedures

POLICY FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH	4-0115 RESEARCH November 2011
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PURPOSE

1.01 The purpose of this policy is to formalize Oklahoma State University's (hereinafter referred to as OSU or the University) obligation to protect human subjects and confirm the University's commitment to its Institutional Review Boards (IRBs), which provide initial review and continuing oversight of research involving human subjects. Therefore, OSU will ensure that each IRB has meeting space and sufficient staff and technology to support an IRB's review and recordkeeping duties.

1.02 OSU, guided by ethical principles pertaining to research involving human subjects and bound by federal regulations, has an ethical obligation to safeguard the rights and welfare of people who volunteer to participate in research conducted under the auspices of the University. Consequently, OSU assures its compliance with the pertinent Federal regulations Title 45 Code of Federal Regulations Part 46 (45 CFR 46 "Basic HHS Policy for the Protection of Human Subjects") as implemented by the United States Department of Health and Human Services (HHS), Title 21 Code of Federal Regulations Parts 50 and 56 (21 CFR 50, 56) as implemented by the United States Food and Drug Administration (FDA), Title 21 Code of Federal Regulations Part 312 (21 CFR 312 "Investigational New Drug Application") as implemented by FDA and HHS, Title 21 Code of Federal Regulations Part 812 (21 CFR 812 "Investigational Device Exemptions") as implemented by FDA and HHS, and the terms of the Federalwide Assurance (FWA) for institutions within the United States. To this end, OSU requires that, prior to initiation of any human subjects research related activities (i.e., prior to recruitment of subjects and data collection), all *research* (as defined below) involving human beings as subjects of research, including research with human material obtained from living individuals, be reviewed and approved by the appropriate IRB.

STATEMENT OF PRINCIPLES

2.01 OSU adheres to the 1979 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”). The ethical principles of beneficence, justice, and respect for persons, as espoused via the Belmont Report, guide the University’s Institutional Review Boards (IRBs) and researchers in meeting their obligations and responsibilities. Therefore, OSU affirms that all of the University’s human subjects research activities will be guided by the ethical principles in The Belmont Report.

2.02 In its commitment to academic freedom, the University acknowledges its responsibility for protecting the right of faculty and other researchers to conduct research in the pursuit of knowledge, as scholars are guaranteed certain freedoms and accept corresponding responsibilities. In the conduct of research, investigators must respect the rights, values, and decisions of people, most particularly through the informed consent process.

2.03 Researchers must treat human subjects in an ethical manner by respecting their personal autonomy and safeguarding their rights and welfare. Moreover, researchers are obligated to maximize possible benefits and minimize potential harms to human subjects. Accordingly, the risks and benefits of research with human subjects should be distributed fairly and without bias.

DEFINITIONS

3.01 *Research* is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102[d]). A research project is typically described in a protocol that sets forth specific objectives and systematic procedures designed to reach the stated objectives.

3.02 *Human subject* means “a living individual about whom an Investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information” (45 CFR 46.102[f]). *Intervention* “includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.” *Interaction* includes “communication or interpersonal contact between investigator and subject.” *Private information* includes “information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record or a student record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the Investigator or associated with the information) in order for obtaining the information to constitute research involving

human subjects.” Private information does not include information pertaining to a corporation or other form of business even if data are obtained through interaction with human beings so long as the elicited data relate to the business and not to the individual.

3.03 *Covered entity* means a health plan, a health care clearinghouse, or a health care provider that transmits certain health information in electronic form in connection with a transaction for which the United States Department of Health and Human Services (HHS) has adopted a standard (The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191).

3.04 *Hybrid entity* is a single legal entity that is a covered entity, performs business activities that include both covered and non-covered functions, and designates its health care components as provided in the Privacy Rule. The Privacy Rule generally applies only to a hybrid entity’s designated health care components; its non-health care components may be business associates of its health care components. A covered entity that does not designate its health care components as provided in the Privacy Rule does not qualify as a hybrid entity and is subject in its entirety to the Privacy Rule (The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191). The HIPAA Privacy Rule governs the use and disclosure of “protected health information” (PHI). The Privacy Rule governs all PHI in all forms, whether electronic, paper, medical media, or conversation.

3.05 *Protected health information* (PHI) is information created or received by a health care provider, health plan, or health care clearinghouse that relates to the past, present or future physical or mental health of a person. Information about payments for health care may also be PHI. To qualify as PHI, the information must identify the person directly or be sufficiently specific that the person could be identified.

SCOPE AND APPLICABILITY

4.01 This policy is designed to conform to Title 45 Code of Federal Regulations Part 46 (45 CFR 46), Title 21 Code of Federal Regulations Parts 50 and 56 (21 CFR 50, 56), Title 21 Code of Federal Regulations Part 312 (21 CFR 312), and Title 21 Code of Federal Regulations Part 812 (21 CFR 812).

4.02 This policy governs the review and conduct of all *research* involving human beings as subjects of research, including research with human material obtained from living individuals, as well as all other activities which even in part involve such research, performed by individuals acting as agents (e.g., faculty, researchers, staff, students, and employees) of OSU, including all institutional components listed via OSU’s respective Federalwide Assurances (FWA00000493 for OSU-Stillwater and OSU-Tulsa, and FWA00005037 for OSU-Center for Health Sciences) with the United States Department of Health and Human Services’ Office for Human Research Protections (OHRP).

4.03 This policy applies to all OSU campuses. Therefore, this policy applies to all *research* involving *human subjects* conducted completely or partially at or sponsored by

Oklahoma State University-Stillwater, Oklahoma State University-Tulsa, the Oklahoma State University Center for Health Sciences, Oklahoma State University-Oklahoma City, and Oklahoma State University Institute of Technology, including (a) research conducted by faculty, researchers, staff, students, and employees; (b) research performed on or in OSU property, facilities, or IRB approved off-site locations; (c) research involving the use of OSU's nonpublic information to identify or contact prospective research subjects; and/or (d) research supported by government funding, industry sponsors, non-profit entities, or by OSU resources and/or facilities regardless of funding source (if any).

4.04 Specifically, the Institutional Review Boards of Oklahoma State University-Stillwater and the Oklahoma State University Center for Health Sciences (OSU-CHS) review and monitor human subjects research conducted by or under the direction of any individual acting as an agent of the University. OSU-Stillwater and OSU-CHS have reciprocal Written Authorization Agreements that are recognized by the Office for Human Research Protections (OHRP) to accept approval decisions made by the other institution's IRB when research protocols involve both institutions or as deemed appropriate, based on the expertise of a respective institution's IRB. Decisions regarding which IRB should review the research will be based on the Written Authorization Agreements and the Standard Operating Procedures of the respective IRBs and administrative support offices (for the Center for Health Sciences' SOPs see <http://www.healthsciences.okstate.edu/research/rsp/irb.cfm> or contact the respective campus offices).

4.05 Oklahoma State University's *covered entities* will meet all guidelines related to the Health Insurance Portability and Accountability Act (HIPAA). Most of the requirements of the HIPAA Privacy Rule apply only to the health care components of the campus.

4.06 If a researcher acting as an employee or agent of OSU conducts research involving human subjects without first obtaining prospective review and approval of an OSU IRB, neither Oklahoma State University nor the Board of Regents for the Oklahoma Agricultural and Mechanical Colleges will be obligated to defend or indemnify the researcher if a human subject initiates legal action, most particularly when there is willful disregard for the rights and welfare of human subjects. The University retains the right to implement review and disciplinary action against anyone who, as an agent of the University, conducts research in a manner that violates Federal regulations, State statutes, and/or this policy. This includes exercising the right to use all options under other University policies. The respective IRB has the authority to make decisions about the use of data gathered without IRB approval.

4.07 This policy supersedes all previous OSU policy statements pertaining to the protection of human subjects.

POLICY AND PROCEDURES

5.01 In accordance with legally binding Federal regulations concerning the protection of human subjects (Title 45 Code of Federal Regulations Part 46 [45 CFR 46], Title 21 Code of Federal Regulations Parts 50 and 56 [21 CFR 50, 56], Title 21 Code of Federal Regulations Part 312 [21 CFR 312], and Title 21 Code of Federal Regulations Part 812 [21 CFR 812]), OSU fulfills its obligation and responsibility through support of its Institutional Review Boards (IRBs), which are established in accordance with the aforementioned regulations. These IRBs are appropriately constituted and empowered under the auspices of the University's executive authorities and by Federalwide Assurances (FWA) with the United States Department of Health and Human Services' (HHS) Office for Human Research Protections (OHRP). IRBs determine that risks to human subjects are minimized and that the risks posed by participation in research are reasonable in relation to the knowledge expected to result. IRBs constituted in compliance with Federal regulations and registered with OHRP have the authority and responsibility to ensure that research is designed and conducted in a manner that safeguards the rights and welfare of human subjects. In performing a comprehensive review, the IRBs must consider ethics, science, and conflicts of interest. Expressly, OSU IRBs:

- A. shall review, approve, require modifications in order to secure approval, and/or disapprove all research activities that fall within IRB purview, including proposed amendments based upon consideration of the risks and potential benefits of the research.
- B. shall require legally effective documentation of informed consent, or when appropriate assent and/or parental permission supported by documentation, or waive documentation of consent.
- C. may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in 45 CFR 46.116(d), or may waive the requirements to obtain informed consent provided the IRB finds and documents that:
 1. the research involves no more than minimal risk to the subjects;
 2. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
 3. the research could not practicably be carried out without the waiver or alteration; and
 4. whenever appropriate, the subjects will be provided with additional information after participation (45 CFR 46.116(d)).
- D. may observe or have a third party observe the consent process and/or the research of any study that falls within IRB purview.
- E. shall require that information provided to subjects as part of the consent process is in accordance with relevant Federal regulations.
- F. shall notify researchers and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a

statement of the reasons for its decision and give the researcher an opportunity to respond in person or in writing (45 CFR 46.109(d)).

- G. shall conduct continuing review of research at intervals appropriate to risks posed to subjects, but not less than once every twelve months, excluding research that qualifies for exemption. Continuing review requires the submission of progress reports by researchers and post-approval monitoring of any study under IRB purview.
- H. may seek appropriate resources in order to conduct thorough reviews of research activities that fall within IRB purview.
- I. may determine that certain research projects need verification that no material changes have occurred since the previous IRB review from sources other than the primary researcher or research team. Therefore, the University's IRBs have the authority to obtain this verification.
- J. shall review, accept, and/or reject reports, including but not limited to reports of serious adverse events and unanticipated problems involving risks to subjects or others.
- K. may suspend or terminate IRB approval.
- L. may place restrictions on any study that falls within IRB purview.

5.02 This policy shall be reviewed and modified as needed by members of the respective IRBs. At a minimum, review of this policy shall take place at least once every four (4) years.

5.03 The IRB is responsible for conducting initial and continuing review of research involving human beings as subjects, including research with human material obtained from living individuals, as well as ongoing oversight of the ethical conduct and risks associated with research. It is the responsibility of the IRB to ascertain that all projects reviewed by the IRB conform to pertinent Federal regulations, State statues, and OSU policies and assist researchers in complying with these regulations and policies. IRBs are responsible for ensuring that research is ethically sound and conforms to the ethical obligations codified by Federal, State, and local regulations.

5.04 In compliance with Federal regulations (45 CFR 46.112), the institution, its officials, or other institutional committees may not override a decision by the respective OSU IRB to disapprove a study. However, research covered by this policy that has been approved by an OSU IRB may be subject to additional review and approval or disapproval by officials of the University.

5.05 The IRBs shall not allow any IRB member to participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the respective OSU IRB.

5.06 Each IRB is responsible for reporting to the appropriate Institutional Official (IO) and/or OSU Vice President for Research any noncompliance with the requirements and determinations of the IRB. The IO of the Stillwater and Tulsa campuses of Oklahoma State University and the IO of the Oklahoma State University Center for Health Sciences have oversight responsibility for the respective institution's human research protection programs. As such, the IOs are responsible for reporting to the OHRP and/or the FDA any serious or continuing noncompliance with Federal regulations governing research involving human subjects or the requirements or determinations of the IRB(s), as well as suspensions and terminations of IRB approval and any unanticipated problems involving risks to subjects or others.

5.07 If a research proposal involving human subjects will be submitted to a prospective sponsoring agency, a research protocol must be submitted to the appropriate IRB for review and approval prior to recruitment of human subjects and data collection.

References

Federalwide Assurance for the Protection of Human Subjects: Terms of the Federalwide Assurance (FWA) for Institutions within the United States. U.S. Department of Human Services, Office for Human Research Protections
<http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm>

Title 45 Code of Federal Regulations Part 46 (45 CFR 46) – United States Department of Health and Human Services

Title 21 Code of Federal Regulations Parts 50 and 56 (21 CFR 50, 56) – United States Food and Drug Administration

Title 21 Code of Federal Regulations Part 312 (21 CFR 312 “Investigational New Drug Application”) – United States Food and Drug Administration and United States Department of Health and Human Services

Title 21 Code of Federal Regulations Part 812 (21 CFR 812 “Investigational Device Exemptions”) – United States Food and Drug Administration and United States Department of Health and Human Services

Title 45 Code of Federal Regulations Parts 160, 162, and 164 – United States Office for Civil Rights

The Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. § 1232g; 34 CFR Part 99)

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1979). *Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (The Belmont Report) (DHEW Publication No. OS 78-0013 & No. OS 78-0014). Washington, DC: U.S. Government Printing Office.

Additional References

Declaration of Helsinki

The Nuremberg Code

Oklahoma Statute, 63 O.S. §2601 *Oklahoma Public Health Code(Public Health & Safety)*

State of Oklahoma *General Records Disposition Schedules for State Universities and Colleges* (www.odl.state.ok.us/oar/recordsmgmt/grds-education.htm).

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