**OKLAHOMA CHRISTIAN UNIVERSITY**

**Research Using Humans Policy**

Researchers conducting human subjects research are REQUIRED to comply with:

**Federal Legislation**: [Code of Federal Regulations Title 45 Part 46 (45CFR46)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html)

**State Legislation**: Federal regulations require researchers to conduct research in compliance with applicable state law. Investigators must comply with Oklahoma state laws as they pertain to human participant research.

**Specific Oklahoma Policies for Research Involving Protected Populations:**

**Emancipated Minors**

Under O.S. §63-2601, any minor who is married, has a dependent child, or is emancipated (released from parental or guardian control and is not supported by the parents or guardian) may consent to certain health services. Health services do not include research or experimentation except when the research or experiment is an attempt to preserve the life of that minor or research as approved by an appropriate review board involved in the management of reportable diseases.

**Cognitively Impaired Individuals**

Under O.S. §63-3201A, under certain conditions consent of a cognitively impaired individual to participate in a research project may be obtained from a legal guardian, attorney-in-fact with health care decision authority, or a family member (in the following order: spouse, adult child, either parent, adult sibling, or a relative by blood or marriage). However, if cognitively impaired individuals were legally competent to express permission or prohibition prior to becoming cognitively impaired, the legal guardian or family member cannot override the individual’s previously expressed permission or prohibition.

**Fetal Materials**

Under O.S. §63-1-735, research on fetal tissue resulting from an abortion is prohibited. An abortion is defined as the purposeful termination of a pregnancy with an intent other than to produce a live birth or remove a dead unborn child. The use of fetal tissue resulting from a spontaneous miscarriage for research purposes is not specifically prohibited.

**Other Applicable State Laws:**

**Disclosure of Genetic Research Studies**

Under O.S. §36-3614.4, all research records of individual subjects in genetic research studies shall be confidential.

**Human Cloning**

Under O.S. §63-1-727, human cloning is unlawful.

**Human Subjects Protection**

Oklahoma Administrative Code, Title 310, Oklahoma State Department of Health, Chapter 10. Human Subjects Protection defines the responsibility of the Oklahoma State Department of Health to provide an organizational structure in accordance with 45CFR46 to establish and maintain an environment dedicated to the ethical principles for safeguarding the rights and welfare of the human beings recruited to participate in research activities.

There are other state laws that could extend to the research being conducted. For example, state law requires that any person having reason to believe that a child under the age of 18 is a victim of abuse or neglect shall report the matter to the Department of Human Services. This state law is not specific to or even related to research; however, during the conduct of research, personnel could become aware of child abuse or neglect and would be required to report the abuse under state law.

**Overall Summary of OC IRB:**

Oklahoma Christian University has established an Institutional Review Board (IRB) to review all proposed research involving human subjects to ensure that the subjects' rights and welfare are adequately protected. The IRB is composed primarily of faculty members from disciplines in which research involving human subjects is integral to that discipline's work, as well as two members from the community whose primary interests are non-scientific. The human subjects review process is administered through the Office of Academic Affairs. Researchers are REQUIRED to comply with the Oklahoma Christian University “Procedures for Review of Human Subjects Research”.

**Application Process and IRB Meetings:** All human subject research proposals must be submitted to the IRB. Researchers whose study is not federally regulated (i.e., is not federally funded and does not take place on federal property) and who believe their study is exempt from state law shall complete an application for exempt research. See the Application Form for Exempt Research, which is Appendix 1. Submit the application and associated materials to the IRB Chair. All others must complete the Human Subject Research Review Application Form, which is Appendix 2. The responsible project investigator (RPI), or a member of the research team familiar with the project, may be requested to attend the Institutional Review Board (IRB) meetings regarding the project. The application and associated materials should be separated into the following different files:

* Application Form
* Human Subjects Training Documentation
* Informed Consent Documents
* Recruitment Documents
* Study Materials and/or Instruments - separate .pdf files should be created for each distinct cluster of materials or instruments (i.e. - separate files for multiple surveys)
* Grant/Contract Information (if applicable)

Files should be saved with the investigator's last name followed by the information in the .pdf (ex - "Luttrell\_application", "Luttrell\_trainingdoc", etc...). The application and all other materials should be sent electronically to Dr. Jonathan P. Miller, Chair, OC Institutional Review Board, at irb@oc.edu or mailed to Oklahoma Christian University, 2801 E. Memorial Rd., Edmond, OK 73013-6474. Depending on the complexity of the application and other supporting materials, the review and approval process of the OC IRB can require two to four weeks to be completed.

**Expedited Reviews:** The Oklahoma Christian University IRB conducts Expedited Reviews. According to this policy, Expedited reviews are allowed in two instances:

1) The research protocol has undergone review at another institution and has obtained approval from that institution, or

2) Minor changes are being proposed to a previously approved research protocol.

If your protocol qualifies for Expedited Review, you may submit an electronic copy of the research application to the IRB Chair. Protocols that have received approval at another institution should include the IRB application and all supporting information submitted to the first IRB, as well an electronic copy of the approval letter from that institution.

**Approval Period:** The approval period for a study is typically one year. Researchers must submit a Progress Report if a non-exempt project is to last longer than the approval period, which is typically 1 year. Researchers must submit the Progress Report Form, which is Appendix 3, to the Chair of the IRB two months prior to the study's expiration following the electronic submission procedure. The study must be reviewed and re-approved by the IRB for research to continue. Non-exempt studies are considered complete when data collection and data analysis are complete. Researchers must submit 1 copy of the Close Out Report, which is Appendix 4, to the Chair of the IRB 1 month after the study is complete.

**Forms:** All forms pertaining to research involving human subjects can be downloaded from the OC Institutional Review Board (IRB) website.

**Training:** All human subject researchers and IRB committee members must obtain adequate training. Online training is available from the U.S. Department of Health & Human Services (HHS). All researchers and IRB committee members must complete each of the five lessons within the “[Human Research Protection Foundational Training](https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/human-research-protection-foundational-training/index.html)” course through the HHS Office of Human Research Protections (<https://www.hhs.gov/ohrp/index.html>) and print out (or save electronically) a copy of each of the five lesson completion certificates to be placed on file by the Chair of the IRB. All lessons need to have been completed within the past 36 months.

In addition, Investigators who propose studies with patient populations are required to document HIPAA (Health Insurance Portability and Accountability Act) training. Investigators must access the National Institutes of Health (NIH) booklet entitled "Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule" at:

<https://privacyruleandresearch.nih.gov/pr_02.asp>

Investigators must submit an attachment to the review application stating that the material has been read and will be adhered to in the proposed research. The attachment must include the date the material was read, which must be within the 12 months prior to the application.

**Resource:**  Researchers can review a list of “Frequently Asked Questions (FAQ’s) About Human Subject Research at OC”.