OKLAHOMA CHRISTIAN UNIVERSITY

FREQUENTLY ASKED QUESTIONS (FAQ’s)

ABOUT HUMAN SUBJECTS RESEARCH AT OC

**What is human subject research?**

It is a systematic investigation designed to expand knowledge by obtaining data from a living individual, using an intervention (written survey) or interaction (interview) between a researcher and another person; or using the collection of identifiable private information (physical procedures such as venipuncture, observation of behavior while manipulating a person’s environment, or review of personal records).

**When should projects involving human subjects be reviewed?**

All research involving human subjects must be reviewed and approved before data collection can occur to assure that subjects are being treated ethically.

**Should I submit my proposal to the Institutional Review Board (IRB)?**

If you think that your study is exempt and the study is not federally supported, submit the proposal to the IRB using the Application Form For Exempt Research.

If your study is not exempt or if the study is federally supported, submit your proposal to the IRB using the Human Subjects Research Review Application Form.

**Are classroom student research activities considered human subject research?**

Student class projects involving human subjects conducted under faculty supervision that are intended to provide instruction or training in research methods are best treated as human subject research (HSR), because of the participation of others and the collection of data. The faculty member is the responsible project investigator. Where possible and appropriate, student projects should be designed to meet an exemption (such as using anonymous human subjects or limiting survey data to non-sensitive topics with no other risk). Any faculty member who uses human subjects in a research practicum or student project must apply for review and approval by the IRB.

**What are the deadlines for submission to the IRB?**

The researcher shall submit the original or an electronic copy of the entire proposal and the proposed informed consent document to Dr. Jonathan P. Miller, Chair, Institutional Review Board, Oklahoma Christian University, 2501 E. Memorial Rd., Edmond, OK 73013, or an electronic copy of the entire proposal and the proposed informed consent document to irb@oc.edu. All submissions are due by 5 p.m. on Thursday two weeks prior to the IRB meeting on Tuesday.

**Does the responsible project investigator (RPI) have to attend an IRB meeting?**

If requested, the RPI or a member of the research team familiar with the project, should attend the Institutional Review Board (IRB) meetings regarding the project. The Chair of the IRB will notify the RPI when it is necessary for attendance at an IRB meeting, such as when questions have arisen concerning the review of the research proposal.

**How often does the IRB meet?**

The IRB meets monthly except for the month of July. For dates, go to the IRB website.

**How long will it take to get a response from the IRB?**

The IRB reviews proposals at each meeting. Studies are approved, approved with modifications, or disapproved. The Chair of the IRB will notify you within a few days of the IRB meeting regarding the IRB vote and whether any modifications to your proposal are necessary.

**What is a Responsible Project Investigator (RPI)?**

A RPI is a faculty or full-time staff member who assumes the responsibilities below. A student may not serve as an RPI. The RPI is responsible for:

* Submission of all required forms to the IRB;
* Conduct of the research;
* Compliance with IRB decisions;
* Submitting proposed changes to previously approved research.

**How do I complete IRB application forms?**

* Answer every question fully
* If you are using the Human Subject Research Review Application Form (Appendix 2), be sure to enter a brief but accurate description of the procedures in item #11; do not say "see attached".
* Type the application. Handwritten applications will be automatically rejected.
* Append to the application form:
	+ research protocol (for funded proposals)
	+ data collection instruments
	+ surveys/questionnaires
	+ recruitment materials
	+ other pertinent information

**How do I write an informed consent document?**

* Use the OC template
* Write in language understandable to the subject
* Include timeline for procedures – duration of each visit, total duration of study
* Use proper grammar
* Spell check
* Make sure that information in the informed consent matches the application
* Include local phone number for subjects to call with questions

**What projects receive expedited review?**

The IRB Chair performs expedited reviews in 2 instances:

* a collaborative project has already been approved by a separate IRB
* a revision is being made to a project already approved by the OC IRB

**What is the application process for studies that have been approved by another IRB?**

The IRB Chair can perform an expedited review, since the research is already approved by another IRB. The RPI must send the IRB Chair a copy of the other IRB approval letter and all application materials submitted to the other IRB. If the project utilizes an informed consent document, the informed consent form will need to be modified to include references to OC, the IRB, and the IRB Chair.

**A researcher from off campus wishes to perform a study at OC without an OC collaborator. What type of review is needed?**

The action needed by the RPI is to submit the IRB approval letter and application materials from another institution to the IRB Chair. The IRB Chair will then check to see if there is any obvious problem with allowing the study to proceed. If there are no problems, then the IRB Chair will inform the RPI that he or she may proceed.

**What type of training is required for investigators?**

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; see link below).

All RPIs, proposing non-exempt research must document completion ***each of the five lessons*** of 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) (<https://www.hhs.gov/ohrp/education-and-outreach/online-education/human-research-protection-training/human-research-protection-foundational-training/index.html>) within the past 36 months. A copy of the RPI’s “Human Research Protection Foundational Training” certificates from each of the five lessons must accompany proposal applications to the IRB. RPI’s must ensure training of all personnel, but submission of these certificates is not required by the IRB. In other words, all researchers listed on the application materials should complete the training listed above; however, only the RPIs certificates need to accompany the application for review.

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>

**When can I start collecting data?**

You cannot start collecting data until you have an IRB approval letter in hand! You must conduct the study according to the approved protocol and IRB conditions.

**What happens if I want to make a change to the protocol after the study is approved?**

Submit ANY proposed changes directly to the IRB Chair for review and approval before implementing them. Such changes include:

* Alteration of study design, methodology, or recruitment methods
* Changes to any instruments, including surveys and questionnaires
* Changes to informed consent documents
* Addition/deletion of investigators
* Alteration of project title
* Addition of research sites

Changes to exempt studies do not need review unless the change makes the study non-exempt.

**What is an adverse event (AE)?**

An adverse event is any illness, injury, trauma experienced by a subject during the course of a study that required medical or psychological treatment. Such events may occur during data collection or outside of data collection, at the research site, or away from the research site. A serious AE is one that resulted in death, life threatening situation, inpatient hospitalization, significant disability, or a birth defect. An unexpected AE is an adverse event that is not currently listed in informed consent.

**What type of adverse events should be reported and how?**

All adverse events should be reported, even those that do not appear to be related to the study.

* Serious or Unexpected: Report to IRB within 5 days; use AE form (If serious, physician comment required)
* Neither Serious nor Unexpected: Report to IRB within 1 month; use AE form

**Can I do a study for more than a year?**

Submit a progress report if a non-exempt project is to last longer than the approval period, which is typically 1 year. Submit the original and an electronic copy of the Progress Report to the IRB Chair 2 months prior to the study’s expiration. The study must be reviewed and re-approved by the IRB for research to continue.

**When is a study complete?**

Non-exempt studies are considered complete when data collection and data analysis are complete. Submit the original and an electronic copy of the Close Out Report to the Chair of the IRB within 1 month after your study is complete.

**If you have additional questions, please contact:**

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