



OSU HUMAN SUBJECT RESEARCH PROTECTION (IRB) STEP-BY-STEP

It is the policy of Oklahoma State University that all **research** involving **human subjects** conducted by faculty, students, or staff of OSU shall be submitted to the OSU Institutional Review Board (IRB) for review **before** the research is initiated.

STEP 1: REVIEW HUMAN SUBJECT RESEARCH WEBSITE AND/OR HANDBOOK FOR PROTECTION OF HUMAN SUBJECTS IN RESEARCH

STEP 2: DETERMINE IF PROJECT IS RESEARCH WITH HUMAN SUBJECTS (NEED FOR IRB REVIEW)

STEP 3: COMPLETE REQUIRED TRAINING

STEP 4: IRB APPLICATION PREPARATION AND REVIEW

STEP 5: PROTOCOL MODIFICATION/ADVERSE EVENT REPORTING

STEP 6: PROTOCOL CONTINUATION/CLOSURE



STEP 1: REVIEW HUMAN SUBJECT RESEARCH WEBSITE AND/OR HANDBOOK FOR PROTECTION OF HUMAN SUBJECTS IN RESEARCH

The OSU Institutional Review Board (IRB) website, <http://compliance.vpr.okstate.edu/IRB/irb-index.aspx>, and the OSU Handbook for Protection of Human Subjects in Research are a valuable resource for information on the protection of human subjects in research and the IRB application and review process at OSU. Here you will find information to help you determine the need for IRB review, how to apply to the IRB for review, forms and training requirements. Contact information for the IRB Chair, members and staff is also provided.

STEP 2: DETERMINE IF PROJECT IS RESEARCH WITH HUMAN SUBJECTS (NEED FOR IRB REVIEW)

To determine if your project requires IRB review you will need to assess if it meets the definition of **research** and if **human subjects** are truly involved. The regulatory definitions of research and human subject can be found on the IRB website at <http://compliance.vpr.okstate.edu/IRB/definitions.aspx#Research>. A quick guide for determining the need for IRB review is available on the IRB website at http://compliance.vpr.okstate.edu/IRB/need_for_IRB.aspx.

For some categories of research it is difficult to determine whether they qualify as **human subject research**. To assist with this determination and to provide documentation of the decision, the IRB has developed a form, Request for Determination of Non-Research, Non-Human Subject found on the IRB website at <http://compliance.vpr.okstate.edu/IRB/forms.aspx>. This form should be completed by any OSU researcher that is unsure of the need for IRB review of their project. The form will be reviewed by the IRB Manager or IRB Chair, signed and returned to the researcher as documentation of the decision. Copies of the form will be retained in the IRB office.

STEP 3: COMPLETE REQUIRED TRAINING

Oklahoma State University requires that all principal investigators conducting research involving human subjects (faculty, staff or student) complete a training program in basic human subjects protection, regardless of whether the research is funded or not or the source of funding. The basic training is provided through an online web-based course provided through the Collaborative IRB Training Initiative (CITI) hosted by the University of Miami. Information on the required training program and links to the online training web site can be found on the IRB website at <http://compliance.vpr.okstate.edu/IRB/training.aspx>.

Who Must Train?

- **OSU Principal Investigators and Advisors**
Any OSU faculty member, staff member or student who is listed as a principal investigator in a research project that involves human subjects, or who is acting as advisor to a student conducting such research, must complete the required CITI training modules prior to submission of a protocol. PIs are responsible for ensuring adequate training of their personnel.
- **OSU IRB Members/Alternates and IRB Staff**
IRB members, alternate members and IRB staff are required to complete the required CITI training modules within three months of their appointment to the IRB.
- **OSU Institutional Officials**
The Vice President for Research, University Research Compliance Director, Associate Deans for Research and Department Heads are required to complete the CITI training modules required for OSU administrators.

STEP 4: IRB APPLICATION PREPARATION AND REVIEW

The OSU Office of University Research Compliance coordinates the IRB application and review processes. The IRB website <http://compliance.vpr.okstate.edu/IRB/irb-index.aspx> will link you to information, forms, and meeting dates that will assist you in the application process.

The OSU IRB application form is available electronically; it can be accessed and downloaded from the IRB web page <http://compliance.vpr.okstate.edu/IRB/forms.aspx>. The University Research Compliance IRB staff is available at any time to assist with completion of the application form and to answer any questions about the required supporting documents.

IRB applications will be reviewed by the IRB at one of four levels:

- Exempt
- Expedited
- Expedited Special Population
- Full Board

The PI designates the level of review when the application is submitted. The level of review depends on an evaluation of the potential risk and benefits to the human subjects, whether the subjects include members of special population (see the IRB website) and the federal guidelines that define the review process. Information to help in determining the appropriate level of review can be found on the IRB website at <http://compliance.vpr.okstate.edu/IRB/application-det.aspx>.

Before you submit your IRB application, be sure:

- To read the Guide to Completion of the IRB Application Form, found on the IRB website at <http://compliance.vpr.okstate.edu/IRB/forms.aspx>.
- You are using the most recent version of application
- Everyone who signs the application has completed the required human subjects protection training
- All signatures have been obtained (PIs, Advisor, Department Head, Associate Dean for Research)
- Short version vitas for all PIs and Advisor are attached
- To include permission from study location if it is different institution located off campus
- If your application requires full board review, be sure you turn it in before the meeting deadline
- To include informed consent/assent forms
- To include recruiting materials including scripts, letters, or flyers to be provided prior to subjects' agreement to participate
- To include copies of all instruments such as questionnaires, surveys, tests, screening forms
- To include copy of grant proposal if project is funded

One original copy of the complete, signed application including all required attachments must be submitted to the IRB office located in University Research Compliance office in 219 Cordell North. The schedule for submission of your application is dependent on the level of review.

Type of Review	Submission
Exempt Status	Any time
Expedited	Any time
Expedited Special Population	Any time
Full Board	14 days prior to meeting date (posted on web site)

PIs should be sure to allow ample time for review, keeping in mind that IRB committee members have other full-time positions. Most exempt status and expedited reviews can be accomplished in seven to ten days. Expedited special population and full board reviews will take longer.

STEP 5: PROTOCOL MODIFICATION/ADVERSE EVENT REPORTING

Your research activities must be carried out within the parameters of the approved protocol. Any change to the protocol, whether in design, sampling, recruitment of subjects, consent procedures, etc. requires an official modification request and approval. Modification of a protocol does not change the original approval expiration date.

A request for a modification of an approved protocol must be made in writing by completing the Modification form available for download from the IRB website <http://compliance.vpr.okstate.edu/IRB/forms.aspx>. One copy of the Modification form and any revised materials are to be submitted to the IRB office in the Office of University Research Compliance, 219 Cordell North.

Adverse events are those which cause unanticipated harm to subjects or others. Unanticipated problems involve risks that are not explained in the consent process. To insure compliance with the federal regulations, the OSU IRB requires investigators to report any such occurrence to the IRB Chair within 24 hours of the event. A form for reporting an event or problem is available on the IRB web page <http://compliance.vpr.okstate.edu/IRB/forms.aspx>.

STEP 6: PROTOCOL CONTINUATION/CLOSURE

Ensuring responsible conduct of research is an on-going process. Federal regulations require the continuing review of human subjects research by the IRB at intervals appropriate to the degree of risk, but not less than once per year. The goals of this process are to re-evaluate the acceptability of the risk/benefit ratio and the safeguards for subjects, and to confirm that the approved protocol has been followed. **Any research activity initially reviewed and approved by the OSU IRB is subject to continuing review.**

PIs will be notified by the IRB office that a protocol renewal date is approaching 60 days prior to the first of the month of the protocol expiration date. A second notice will be sent 30 days prior to the first of the month of the protocol expiration date. If the PI does not request closure or submit a Continuation/Renewal form prior to the expiration date of the protocol, the PI will be notified that IRB approval of the protocol has expired and that the protocol has been closed. **If protocol approval lapses and/or the protocol closed, no human subject data collection may continue without submission and approval of a new application form.**

The required Continuation/Renewal form can be accessed at the IRB website at <http://compliance.vpr.okstate.edu/IRB/forms.aspx>. The Continuation/Renewal form should be accompanied by the current informed consent document, recruitment script, and any **new** materials or instruments to be added to the protocol. **Forms are to be submitted to the IRB office, 219 Cordell North, a minimum of two weeks prior to the expiration date of the protocol.**

CONTACTS

The mission of the IRB staff is to provide for the protection of human subjects participating in OSU research projects while assisting you in attaining your research objectives. We are available to answer any questions or address any concerns you may have. Please feel free to give us a call or drop by our office anytime. The IRB office is located in 219 Cordell North and can be reached at 405-744-3377.

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