

## **Is it Research? If yes, what then?**

This [slide presentation](#) offers the researcher essential background information on federal definitions of research and the activities mandated by federal regulation regarding the protection of the human subjects of research.

## **Who is subject to the purview of the IRB Review Committee?**

All research that is conducted by or under the direction of any employee or agent of Oakwood University (faculty, staff, or student) or in connection with his or her institutional responsibilities is under the purview of this committee. This includes all research, regardless of source of funding or the location of the participating human subjects.

- a. Faculty, staff, and student initiated research is under the purview of this committee. This includes, but is not limited to, data gathering projects and class assignments involving human subjects. The IRB must review proposals if students are conducting research as part of a class assignment, or as part of the requirement for a degree, and the research involves human subjects, records gathered on human subjects, or human tissue
- b. Sole exception: Research conducted in the classroom involving only students enrolled in that course and carried out only for instructional purposes in that course may be undertaken with the understanding that the instructor assumes responsibility for its ethical nature and for the protection of the rights and welfare of students involved.
- c. Research initiated or sponsored by OU faculty/staff/students, that is neither funded by nor based at OU, should be submitted to the OU IRB for approval. This assurance is required even if the research has received approval from a human subjects committee at another institution (See Collaborative Agreements this website).

## **Applying for IRB Approval**

### **1. What kind of research studies require IRB approval?**

Any research studies utilizing human subjects require IRB Approval. The definition of a human subject is a living individual about whom an investigator conducting research obtains data and/or identifiable private information through intervention or interaction with the individual.

### **2. How do I apply for IRB approval?** See “Steps for Applying” under Institutional Review Board this sight.

### **3. When can I expect a decision about my IRB application?**

The length of IRB review depends on the nature of the study. The IRB will generally issue a decision about an application within 4 weeks of receiving the application and all required supporting documents. If an application qualifies for expedited review, this may be shortened to 7-14 days.

### **4. How will I be notified when my IRB application is approved?**

The IRB Office will issue an approval notification by email and/or mail when the decision is made.

## **5. How long is my approval good for?**

Most IRB approvals expire one year from the date of approval (exceptions may occur). However, some research may be considered EXEMPT from continuing IRB review and will not be required to submit a scheduled continuation review (renewal) application on an annual basis. See IRB policies for further information.

## **Consent Forms, Advertisements, Survey Instruments and Other Supporting Documents**

### **1. I've heard there is a requirement for stamping consent forms and advertisements with approval dates and IRB Numbers. How do I do this?**

Submit separate clean copies of these documents for official IRB stamp which will occur at the time of approval by the IRB.

### **2. Is it necessary to have a consent form for a survey?**

Yes. Full written informed consent is required unless the IRB approves a waiver of consent or a waiver of documentation. Please see the "Forms" section.

### **3. What if I only have a draft of my instrument (e.g., survey, questionnaire)?**

Indicate this when prompted in the application, and copy your instrument as a "DRAFT" document in order to provide the IRB with an idea of your intended methodology. After you have finalized the instrument, submit an amended application.

## **Amendments to IRB Approved Research Studies**

### **1. What kinds of changes to my research study necessitate the submission of an amendment application?**

ANY change(s) to an approved research study require submission of an amended application.

This includes:

- Alteration of study design, methodology, or recruitment methods
- Changes to any instruments, including surveys and questionnaires
- Changes to consent documents
- Addition/Deletion of principal investigators or key personnel
- Alteration of Project Title
- Addition/Deletion of research performance sites

### **2. How do I report a change to an IRB approved research study?**

Submit amended application. Remember you must modify the consent form if the proposed changes affect the informed consent process. The IRB will review the changes and you will be notified by email. IMPORTANT: You must wait to receive IRB approval before implementing any proposed amendments.

## **Scheduled Continuing Review/Renewal of IRB Approval**

**1. How often must I renew my IRB approval?**

Federal regulations require that the Institutional Review Board conduct a continuing review of human subject research at least once per year. The continuation of subject recruitment, data collection, or data analysis without IRB approval is prohibited after the expiration date assigned to the project by the IRB. You will be notified by the IRB when your approval is about to expire and it is time to complete your Scheduled Continuing Review.

**2. How do I apply for a Scheduled Continuing Review of my approval?**

To submit a Scheduled Continuing Review (SCR) application. The IRB will review your application and you will be notified by email.

**3. I received an expiration notice from the IRB Office, but I don't intend to seek an extension of my approval (funding expired, data collection and analysis is complete, etc.). What should I do?**

Submit a Final Report form (see Forms).

**4. Do I need to complete a Scheduled Continuing Review (SCR) of my IRB approval if my funding has ended?**

If you are still collecting and/or analyzing data, you must submit a Scheduled Continuing Review (SCR) form (see Forms). If the funding has ended, data analysis is complete, and the only activity is preparing submissions for publication, you do not need to complete an

## **Termination of IRB Approval**

**1. Can I continue to work on my research study if I have received a Final Termination Notice indicating that my approval has expired?**

No. After the approval period for your study has expired, you may no longer continue to work on the study, including collection and analysis of data. The IRB Office issues 3 expiration notices to the PI before automatically terminating the IRB approval of a research study. If you have received a final termination notice, and you plan to continue working on your study, contact the IRB Office to discuss your situation.

**2. I want to terminate my IRB Approval (funding was lost, my study never received funding, data collection and analysis is complete, etc.)? Submit a Termination Application to IRB (See Forms).**

**3. I received an expiration notice from the IRB Office indicating my approval will soon expire. What should I do if I don't intend to renew my approval? Submit a Termination Application to IRB (See Forms).**

## **Adverse Events**

### **How do I report an adverse event?**

How to answer stipulations from the IRB.

Provide a written response to each of the committee's stipulations along with the original signature of the PI on the cover letter.

If changes to the consent documents are required, include revised consent/assent forms with changes highlighted. Include a copy of any documents requested by the committee and highlight any changes made in response to stipulations.