Oglethorpe University Institutional Review Board Information and Procedures

General Information and Procedures

The purpose of an Institutional Review Board (IRB) is to help ensure that researchers observe ethical guidelines developed to protect the well-being of research participants. Under most circumstances, all faculty, staff, and students planning to conduct research involving human participants must obtain approval by the IRB prior to any data collection. Approval also must be obtained prior to any changes in approved procedures that will affect the confidentiality or risk of harm to participants. Most protocols will be approved for one year, although the review interval may be shorter if the IRB determines that the degree of risk is more than minimal. It is the responsibility of the investigator to make sure that ongoing research is submitted for review before the approval lapses. More specific guidelines and recommendations are provided below.

When is it necessary to submit a research project to the IRB for review?

Faculty, staff, and student research that includes human subjects **must** be submitted for review if **any** of the following criteria apply:

1. The research involves interaction with participants, **or**
2. The research collects identifiable data of a personal nature (from participants or records) that the participants would reasonably expect to be confidential, **or**
3. The research involves collecting data from participants from an especially vulnerable population, such as infants, children, people with mental illnesses, prisoners, or people undergoing medical procedures. You should consult with the IRB to obtain more information on relevant safeguards for special populations such as these, **or**
4. The research involves more than minimal risk of physical or psychological harm or discomfort to participants. According to federal regulations (45 CRF 46), minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life. Your assessment of harm and discomfort should include consideration of emotional discomfort such as embarrassment or emotional pain, **or**
5. The research involves deception of the participants at some point in the project, **or**
6. The research project involves the solicitation of external funding. In this case, be aware that as of 10/1/00, the federal government requires that all submissions for federal grants regarding research with humans be accompanied by a certificate of proof that the submitter has completed a course or workshop on the ethical treatment of human participants. Please contact the chair of the IRB for more information on this requirement if it applies to your project.

Research by students that involves human participants can be reviewed and approved through departmental procedures approved by the IRB if **all** of the following criteria are met:

1. The research is not externally funded, **and**
2. The research collects only anonymous data from participants and records, **and**
3. The research does not involve collecting data from participants from an especially vulnerable population (e.g., infants, children, people with mental illnesses, prisoners, people undergoing medical procedures), **and**
4. The research involves no more than minimal risk of physical or psychological harm or discomfort to participants (see definition of minimal risk of harm above) **and**
5. The research does not involve deception of participants

Departments where students frequently use human participants in research projects must develop a procedure for evaluating student projects that meet the five points above. The procedure must be approved by the IRB prior to implementation. The Psychology Department endorses and follows the ethical standards of the American Psychological Association when it evaluates student research projects that meet the five points above. These guidelines are recommended for other departments as well.

Special Note: Individuals outside of the Oglethorpe University community who wish to conduct research on campus must submit their proposals for IRB review.

When is it not necessary to obtain IRB approval or departmental approval?

To address this issue, consider the guidelines adopted by the Department of Psychology. The Psychology Department traditionally uses humans as research participants more than any other department. In that department, human participants are used in research projects in three ways. First, the faculty in the department sometimes use humans as participants in their own projects. For example, one professor measures people's abilities to accurately decode nonverbal forms of communication. Second, the students in our department sometimes use humans as participants in their own projects. For example, a student may create a personality questionnaire and distribute the questionnaire to students via campus mail as part of an advanced research project, independent study, or honors project. Third, instructors in the department sometimes conduct small experiments in class to illustrate a point or to collect data for statistical analysis. For example, one instructor arranges for a person to unexpectedly enter a classroom and "steal" the instructor's notebook. After a passage of time, the students (witnesses) answer a series of questions about what happened. They then use the data to test several hypotheses about eyewitness testimony and memory.

In the first two cases (i.e., faculty and student research), the Psychology Department must follow the IRB guidelines for review and approval. In the third case (in-class experiments), the department believes that these are pedagogical exercises, not research *per se*. Consequently, instructors are given the freedom to use activities that they believe are appropriate, as long as those activities conform to the ethical standards of the American Psychological Association. In short, all research in the Psychology Department will conform to the American Psychological Association's ethical standards and, when appropriate, research projects will be submitted to the IRB for its review.

Departments in similar situations, with similar types of classroom projects, do not need to submit them for IRB or departmental approval. Note, however, that some ethical standards should be adopted and followed even in those pedagogical exercises.

What is the procedure for submitting proposals to the IRB?

The Oglethorpe University IRB conducts two types of reviews, standard and expedited. For a standard review, all IRB members read and review your proposal. For expedited reviews, only the IRB Chairperson will review the request. You may request an expedited review of your research if either of the following two points apply:

1. Your study is an ongoing project that already has been approved by the IRB and has not changed or has changed in a way that will not affect confidentiality or risk of harm to participants. Whether or not changes in the procedures are introduced, all ongoing research must be reviewed by the IRB at least once a year.
2. Your study involves no more than minimal risk of physical or psychological harm or discomfort to participants and does not involve deception or the use of participants from an especially vulnerable population. If the IRB Chairperson is concerned that your study may place participants at risk for more than minimal harm or discomfort, your project will be reviewed through the standard IRB procedures.

The materials to submit for standard and expedited reviews are identical and they should be submitted to the IRB Chairperson. Please submit all required materials through email. For expedited IRB reviews, the procedure normally takes less than one week. For standard IRB reviews, the procedure normally takes about four weeks. Currently, the IRB Chairperson is:

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Oglethorpe University
4484 Peachtree Road, N.E.
Atlanta, GA 30319

Phone: 404-364-8391
Email: lhayes1@oglethorpe.edu

What are the materials to submit for IRB review?

To request approval of your project by the IRB, you need to submit:

1. A completed IRB Approval Request Form (see attached sheet).
2. A copy of your proposed informed consent form (see attached guidelines).
3. Copies of any measures or questionnaires to be used in the study.
4. If the investigator believes that written consent is not appropriate, he or she must provide the IRB with a statement of the reasons why written consent should be waived. Alternatively, a script (which includes all the elements of consent) is sometimes used in obtaining oral consent from the participant. In this case, a copy of the script must be provided to the IRB.

Special Note: Be advised that if you plan to collect data at an off-campus facility (e.g., school, daycare center, hospital) you are responsible for contacting that facility to inquire about its own IRB procedures. In most cases, schools, hospitals, prisons, and other settings have their own IRB procedures. Thus, if your project involves off-campus research, your protocol will need to be reviewed and approved by the Oglethorpe University IRB and possibly by a second IRB at the off-campus facility.

What if an IRB committee member wishes to submit a proposal for consideration?

If a standing member of the committee wishes to submit a proposal, it should be sent to the chair of the IRB for the appropriate type of review (standard or expedited). If the chair of the committee wishes to submit a proposal, she or he will submit it to another member of the committee who will make the decision regarding standard versus expedited review. In all cases, if a standard review is necessary for a committee member's proposal, the submitting member will be excused from all voting responsibilities regarding her/his proposal.

What happens when an approved research project is completed?

The IRB committee asks that investigators notify the committee chairperson once their project is completed and submit a brief summary of the results. This will help the committee keep records on all projects in the event of an external audit of research conducted at Oglethorpe University.

Approval Request Form
Oglethorpe University Institutional Review Board

Date:

Name(s) of Principal Investigator(s):

Department(s):

Phone Number(s) for contact:

Project Title:

Funding: ____ not requesting ____ will request ____ requested ____ obtained from:

Are you requesting a standard or expedited review? ____ standard ____ expedited

Is this project identical to one approved by the IRB within the past 12 months that is ongoing or being sent to a different funding source?

____ yes ____ no

If you answered yes, you need not address criteria 1-6 below. Simply refer the IRB to your earlier submission. If the project is nearly identical, with only subtle changes to a previously approved project, please highlight the changes but do not resubmit all materials. If the project involves changes that will affect confidentiality or risk of harm, you must address all six criteria below.

(Use separate sheets as needed)

1. **Summarize procedures to be used and specify the types of data to be collected. Attach copies of any surveys or questionnaires that will be used. Very specific detail is required about procedures that involve more than minimal harm or discomfort, unusual distress, invasion of privacy, deception, or the use of invasive procedures. In these cases, provide justification for the procedures and explain why alternative methods cannot be used. Also describe specific steps that will be taken to minimize and monitor this risk or stress.**
2. **Describe characteristics of the proposed population of study and summarize the rationale for using any special populations (e.g., infants, children, those with mental or physical disabilities, prisoners) whose ability to give ordinary informed consent may be in question.**
3. **Describe the procedures that will be used to recruit/select participants, obtain data from them, and, when appropriate, debrief them regarding the nature/results of the study. As noted above, very specific detail is required for any procedure that could potentially be harmful.**
4. **Describe how confidentiality will be protected and how participants will be informed of their rights regarding participation in your project (this also should be included in your consent form).**
5. **What are the potential risks and potential benefits to the participants and to the public?**
6. **If there is any aspect of the study that cannot be revealed to the participant(s) prior to beginning the interview or experimentation, please explain and justify. Pay particular attention to explaining and justifying the use of deception and why alternative methods cannot be used.**

Certification of Principal Investigator:

"I certify that I have read and agree to comply with the Oglethorpe University IRB compliance with DHHS Regulations for Protection of Human Research Subjects and that the information I have provided is a true representation of the research to be undertaken. In my judgement, the investigative procedures herein are in conformity with professional standards."

Signature of Principal Investigator: Date:

Guidelines for Obtaining Informed Consent

Oglethorpe University IRB policy regarding informed consent from research participants follows guidelines set forth by the Federal Policy for the Protection of Human Subjects. There may be instances when informed consent is implied without a signed consent document or an oral agreement. For example, a mail survey may be conducted where the basic elements of informed consent are provided in a cover letter. Return of the survey may be viewed as implying the participant consented to participate in the research.

A. Obtaining Informed Consent

1. **Research investigators are responsible for obtaining informed consent as required by the IRB and for ensuring that no human participant will be involved in the research prior to obtaining such consent.**
2. **Unless otherwise authorized by the IRB, research investigators are responsible for ensuring that legally effective informed consent shall:**
    a. **be obtained from the participant or the participant's legally authorized representative. If a legal representative provides consent, the consent form must explain how the representative shall be able to review the progress of the research and for that review to be documented;**
    b. **be in language understandable to the participant or the representative;**
    c. **be obtained under circumstances that offer the participant or the representative sufficient opportunity to consider whether the participant should or should not participate; and**
    d. **not include exculpatory language through which the participant or the representative is made to waive or appear to waive any of the participant's legal rights or releases or appears to release the research investigator, the sponsor, the institution, or its agents from liability for negligence.**
3. **In no instances would it be appropriate for coercive techniques or threats to be used to gain informed consent. An effort always should be made to allow the consenting party to reach his or her decision via a thorough study and assimilation of the information available. Further, if the goals or procedures change as the research project progresses, additional consent shall be obtained; blanket permission shall not be assumed.**

B. Basic Elements of Informed Consent

1. **Unless otherwise authorized by the IRB, research investigators at a minimum shall provide the following information to each participant in the consent form:**
    a. **A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the participant's involvement, a description of the procedures to be followed, and identification of any procedures that are experimental;**
    b. **A description of any reasonably foreseeable risks or discomforts to the participant (including any monetary costs, physical and psychological risks or discomforts);**
    c. **A statement that the particular procedure or treatment may involve risks that currently are not expected and, if such risks become evident as the study progresses, all participants will immediately be informed. Similarly, the consent form should state that any new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided immediately;**
    d. **A description of any benefits to the participant or to others which may reasonably be expected from the research;**
    e. **A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained (e.g., anonymous data, random coding of data, reporting only aggregate data);**
    f. **A statement that participation is voluntary and that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled;**
    g. **A statement specifying an expiration date for the informed consent;**

h. **An explanation of whom to contact for answers to pertinent questions about the research and the research participants' rights. This should include the name, address, phone number, and institutional affiliation of the principal investigator(s). It also should refer the participant to the Chairperson of the IRB if there are any issues that cannot be resolved by the principal investigator(s). Thus, the name, address, and phone number of the Oglethorpe University IRB Chairperson must be included in the form.**
i. **A signed and dated statement by the investigator or a witness stating that the procedures have been read by and/or explained to the participant and the investigator or witness believes the participant has understood the procedures (this usually appears next to the participant's dated signature or the representative's dated signature);**
j. **When research involves more than minimal risk, an explanation about whether there is compensation available and an explanation about whether any medical treatment is available if injury occurs and, if so, what they consist of, or where further information may be obtained. The form also should clearly state whom to contact in the event of a research-related injury to the participant;**
k. **When applicable, a statement that access to participant records (e.g., academic, vocational, medical) will be involved and in what way they will be used;**
l. **When applicable, a disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the participant;**
m. **A statement describing any anticipated circumstances under which the participant's involvement in the study may be terminated by the investigator without regard to the participant's consent;**
n. **The approximate number of participants involved in the study;**
o. **Where recordings, tapes, films, or photographs of a participant are to be made, a statement to this effect should be part of the consent form. If these materials are to be used solely for the purpose of documenting research interviews and if they will be viewed only by the investigator(s) as part of the research project, then further releases are not required. If any other uses are intended or later develop or if individuals other than the investigator(s) view the materials at any time, then further signed releases by the participant are required;**
p. **A statement that the original signed consent form will be maintained by the researcher and the participant will be given a copy for his or her records. Note that some facilities, such as hospitals and prisons, often require a copy of the signed consent form for their records too. Under such circumstances, this should be noted in the consent form.**

2. **Be advised that research involving vulnerable populations, or populations who may not be able to provide truly informed and voluntary consent (e.g., infants, children, prisoners, people with mental or physical disorders, people undergoing medical or psychological treatment) has special requirements. If your project involves a vulnerable population, you should contact the chair of the IRB for more information regarding providing informed consent for these participants.**
3. **In the event that a representative of the participant, such as a parent or legal guardian, is ethically and legally responsible for making decisions regarding consent to participate in a project, every attempt still should be made to gain the assent of the participant.**
4. **Be aware that many projects involving children (anyone under age 18) will require parental consent and the children's assent, depending on the age of the children.**
5. **Researchers are responsible for retaining the consent documents signed by participants for at least seven years with the records of the research protocol. Please note that it may be necessary to retain records for a longer period of time in the future.**