Guidelines and Procedures for

Research Using Human Subjects

Earlham College IRB

Revised Spring 2025

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OVERVIEW

Faculty, staff, and students at Earlham College, the Earlham School of Religion, and in Earlham's Graduate Programs in Education conduct research using human subjects. Such research is regulated by federal guidelines to ensure that the rights of every human subject are protected and that all research is ethical. In addition to federal regulations shared by teaching and research institutions nationwide, we at Earlham take care to protect the integrity of our campus community. Many students conduct research among their peers for pedagogical purposes, and we want to safeguard the privacy, reputation, and physical and emotional well-being of all of our students. This means that we focus on the federal guidelines while assessing research proposals, but also take care to assess the effects of research proposals within our intimate residential environment.

Responsibility to guarantee the ethical and legal soundness of all research undertaken at the College in its various settings is distributed among the individual researcher(s), the program or project supervisor, and Earlham College's Institutional Review Board (IRB). As required by federal policy (45 CFR 46)[1], the IRB consists of at least five voting members. The IRB is under the oversight of the Chief Academic Officer and has been granted Federalwide Assurance (FWA00023058).

No research on human subjects by any participant in any of our programs at whatever level may be conducted without prior IRB review and approval. There are two types of IRB reviews possible, a Full Review or an Expedited Review. In addition, some of the research conducted on campus may qualify as being Exempt from review, however, it is the role of the IRB – not the researcher(s) or faculty sponsor – to determine whether a research project is Exempt from review. The following pages provide information to help researchers determine which of the review types are necessary for proposed research projects. Determinations surrounding approval/disapproval are communicated through the convener of the IRB, after a proposal has gone before the full IRB committee or a subset of IRB members. Should any member of the IRB committee submit a proposal for review, this member cannot be involved in the deliberation or decision-making about her/his proposal.

Finally, when research will involve Earlham students as participants, researchers should be sensitive to the diverse nature of our student body. Special care should be taken to ensure that effects of the research are equivalent across identity groups (e.g., domestic minorities, international students, students with disabilities, etc.). Such consideration should be addressed in the IRB application form. Researchers wishing to collect data from the entire student body (or a randomly selected subset) must clear their research project with the Committee on Assessment and Accreditation, in addition to receiving IRB approval.

[1] Earlham guidelines revised Summer 2017 to comply with the Final Rule Revisions issued January 19, 2017.

COMMITTEE MEMBERSHIP

The responsibility of the members of Earlham's IRB is to make sure that all research associated with Earlham College involving human subjects is ethical, whether that research is conducted on our campus or by members of our campus community in locations off campus. Earlham's values espouse respect for all persons and our IRB is one way by which we can safeguard this value. Ensuring that research is ethical means protecting human participants in terms of their privacy, rights, and well-being (physical, emotional, and psychological).

All IRB members engage in a series of training activities before reviewing any research proposals. These activities help to prepare new IRB members to read and judge the ethical nature of proposals in line with the current federal thinking about the treatment of human subjects of research. In addition, members familiarize themselves with this document detailing the guidelines and procedures of the IRB.

Earlham's IRB meets the Federal Guidelines for the structure of the committee (at least 5 members with at least one from the natural sciences and one from the social sciences, diversity of expertise, and at least one member not associated with the college). Current IRB membership can be viewed at http://earlham.edu/academics/collaborative-research/institutional-review-board/.

DEFINITIONS

In making determinations about research proposals, the IRB uses definitions in line with the Federal code.

The explanations below are how we define these important terms:

- **Research:** a systematic investigation designed to contribute to or develop generalizable knowledge
- **Involvement of human subject:** obtaining information or biospecimens from living human individuals via interaction (communication or interpersonal contact) or intervention (physical procedures or manipulation of the environment)
- **Minimal risk:** activities undertaken while participating in a research project have no more risk than normally occurs in daily life or routine psychological or physical tests
- **Benign behavioral interventions**: interventions that are brief, harmless, painless, not physically invasive, not likely to have a long-lasting impact, and there is no reason to expect that they are offensive or embarrassing (e.g., solving a puzzle under various noise conditions).
- **Clinical trial:** a research study where human participants are assigned to one or more interventions to assess the impact of those interventions on biomedical or behavior health outcomes.
- **Deception:** deliberately mis-informing participants about the nature of the research (e.g., providing false feedback about performance on an exam, etc.). Deception is distinct from *incomplete disclosure*, which is withholding information that could bias your participants' responses (e.g., not telling participants that your research is about racial attitudes, but instead saying it is simply about "attitudes").
- **Broad consent:** consent given to researchers collecting biospecimens from participants so that future research may be conducted with those specimens without additional consent procedures.

FOR RESEARCHERS

IMPORTANT INFORMATION

- Only the exact procedure and materials approved by the IRB should be used in an approved research study. Any changes to an approved protocol **must** be submitted to and approved by the IRB before they can be implemented in a research study.
- The expiration of IRB approval for research proposals varies based on the type of proposal. Full Review proposals are approved for one year from the date of notification of approval. Expedited and exempt proposals do not expire, unless the IRB determines that an expiration date is necessary for a specific proposal. For example, a longitudinal research program of minimal risk may have an expiration date of two or three years, although such a proposal could be renewed.
- For all research, all communication and data should be kept for at least one year, or 3 years after publication.

Required Training

Any person from the Earlham community who is conducting research, as well as those outside the community who wish to conduct research on our campus or within our community, must complete an ethics training module. Earlham's ethics training module can be found on the IRB webpage. The training module includes a brief history of why IRBs are necessary, general information on the basic principles that guide IRBs, and information about issues that applicable to all research (e.g., informed consent) or specific types of research (e.g., research on children). The ethics training module concludes with a quiz, on which researchers are required to receive a score of 70% or better to successfully complete the training module.

No research will be approved unless all individuals named on an IRB proposal have successfully completed ethics training. Once passed, the training module does not need to be completed again, regardless of how many IRB proposals an individual submits.

Informed Consent

Federal guidelines specify that ethical practices for research involving human participants include informed consent by either the participant or the participant's legally authorized representative.

Earlham has two examples of informed consent documents that can be downloaded from the IRB's webpage. **If your research is a federally funded clinical trial, contact the convener of the IRB for a different consent template.** Alternative wording for this document is acceptable, provided that all necessary elements are included or a waiver for some/all elements has been granted (see below). In most cases, participants (or legal representative) will sign a consent form verifying that they have been informed of their rights and consent to participate. For research conducted exclusively online, signing a document may not be practical. In these cases, alternative wording must be provided in an informed consent document (e.g., that providing responses indicates consent).

The necessary elements of an informed consent document are also stipulated by Federal guidelines. This information is necessary in order for participants to make a fully informed decision about their participation in any research. For the majority of research projects, all of the following information must be included in an informed consent document.

1. Researchers must provide participants with the information that a reasonable person would want to have to make an informed decision about whether to participate (e.g., procedures, duration, etc.). Additionally, researchers should answer questions about other aspects of the research if participants inquire.
    a. For research that is medical in nature, any experimental procedures must be identified and any available alternative treatments must be explained.

2. Researchers must inform participants about any possible physical, mental, or emotional discomfort that could arise as part of participation in the specified project. Researchers must do their best to minimize any distress.

3. Researchers must inform participants about any possible benefits, either to participants, society, or the academic discipline. This should include a statement about any compensation (or lack thereof).

4. Researchers must inform participants about their rights regarding the specified research. These include the right to discontinue participation at any time or in any way without negative external consequences, the right to receive a summary of the results, and the right to have a copy of the informed consent document. These rights must be respected by the researcher. For research conducted online, participants should be told to print a copy for their records or contact the investigator for a mailed copy.

5. Researchers must inform participants about what will be done with the data collected and how it will be kept. This includes information about confidentiality or anonymity (if applicable), data storage procedures, and possible publication.

6. Researchers must provide contact information for those who can provide information about the research (generally the researcher) and who can provide information about participant rights (generally the IRB convener).

7. For research involving more than minimal risk, researchers must provide an explanation as to whether any compensation or medical treatments are available if injury occurs.

8. When using research with identifiable data/biospecimens, researchers must include a statement that:
    a. The participant's data/biospecimens will not be used for future research; or
    b. The participant's data/biospecimens might be used for future research without soliciting further informed consent provided identifiers are removed.

Additional elements may be required dependent on the type of research (e.g., for some clinical trials or research with biological specimens not used completely during analysis). The IRB will advise in such cases. Some examples of these new elements are below:

- Whether remaining biospecimens will be used for commercial profit;
- Whether results from a clinical trial will be disclosed to participants; and/or,
- Whether the project might include sequencing of the whole human genome.

Broad Consent

Broad consent, rather than informed consent may be sought in limited cases. This includes storage, maintenance, and secondary research use of identifiable data/biospecimens. If data are going to be made available for other researchers to use (such as on Open Science Framework, osf.io, or any other repository), then this fact should be included in the consent form.

Waiver of Consent

In some research scenarios, obtaining informed consent may be impossible or doing so may undermine the research. In these cases, it is possible for informed consent to be waived. Federal guidelines indicate that informed consent may be waived when **all** of the following conditions are met.

- The research presents no more than minimal risk of harm;
- Removal or alteration of informed consent will not affect the rights or welfare of the participants in a negative way;
- The research could not be carried out without some alteration or waiver of informed consent, whether involving identifiable or non-identifiable private data/biospecimens; and,
- When appropriate, participants will receive information pertinent to their participation after the study.

In these situations, a case must be made to the IRB that standard informed consent is not practical or feasible. Research without informed consent may only occur with IRB approval.

Debriefing

Related to the principle of informed consent is the idea of debriefing. Debriefing is a thorough explanation of the research being conducted, which may include procedures, hypotheses, variables/methods used, etc. Often, this information can be included in the informed consent document. However, there are many times when some or all of this information cannot be included in the informed consent document. For example, participants may not be told that a person they interact with during the study is a confederate (not another participant). This information should then be included in a debriefing document or statement provided at the end of a study.

The IRB **requires** a debriefing document for all studies where deception or incomplete disclosure occurs. Otherwise, debriefing statements are optional according to the IRB, but may still be required by your program, a collaborating partner's institution, or other constituent.

In general, debriefing should occur after every study in which it is possible. Debriefing statements can be written or oral or both, and should provide full clarification about the study, including an explanation of any deception or withholding of information used in the research. Participants should be given opportunities to ask questions following presentation of debriefing information.

There is an example debriefing document available on the IRB's website, but this format will be most helpful for those engaged in experimental or correlational research. The IRB can help other researchers with debriefing statements if desired.

Recordings of Research

Many researchers want to make some type of recording as part of their research project. If any type of video, audio, or visual recording occurs during the research, participants should be given an opportunity to consent to the specific type of recording. As always, participants should not experience negative repercussions if they choose not to participate in research that will be recorded.

Consent for recordings may happen in any of the following ways.

1. Consent for recording can be included in the language of a larger informed consent document. This is likely to happen when engaging in the project without recording would serve no purpose (e.g., studying how people present themselves on camera). If the research is not possible without recording, participants must be made aware that recording is necessary prior to giving informed consent.
2. Consent for recording can be a separate document for participants to sign. This option would be best for research programs wherein research participation is possible without being recorded (e.g., an audio recording is preferred, but written notes are acceptable for the purpose of the research). The IRB has an example of a Recording Consent form which can be downloaded from the IRB's website. As with the general informed consent documents, alternative wording for this document is acceptable.
3. In rare instances, the IRB may approve research protocols where recording occurs without participant knowledge. In these cases, the fact that recording occurred during a research project **must** be divulged to research participants at the end of their involvement in the research. At that point, participants must also be given the option to have the recording of their participation destroyed immediately. At no point can any data be used from a recording without participant consent to record.

Protected Populations

Federal guidelines have additional protections built in for research using specific populations of people. These guidelines are meant to protect groups of people who may be more vulnerable to coercion or undue influence than are other groups. Groups that are specified in the federal code are as follows:

- **Children.** If humans under the legal age of consent (generally age 18) are to participate in research, two levels of consent must be obtained. First, parents or legal guardians of the child must sign a consent form. Second, children must give verbal assent that they agree to participate. A child's absence of refusal cannot be taken as assent.

- **Prisoners.** Research involving prison populations undergoes more rigorous review because prisoners may not have the same ability to make decisions in the absence of coercion. For these research proposals, a member of a prison population must be involved in the determination of approval and the majority of the rest of the IRB cannot be associated with the prison from where the population will be sampled.

- **Individuals with impaired decision-making capacity.** This category may include individuals with Alzheimer's disease, those who have had a stroke or traumatic brain injury, those with developmental disabilities affecting cognition, or others. In general, research using members of these groups requires the consent of a legally authorized representative and the consent/assent of the participant, if consent/assent is able to be given in the context of the research.

- **Economically or educationally disadvantaged persons.** Members of these groups may be more susceptible to coercion than other groups. Thus, care should be taken by the researcher to make sure that no element of coercion is present in the research.

The use of any of these populations for research, unless otherwise exempted from review, requires a Full Review by the IRB. Researchers wishing to use any of these populations are encouraged to read the subparts of the federal code which address the population of interest and/or meet with the convener of the IRB.

USING DECEPTION IN RESEARCH[2]

Disclosure of Research Hypothesis

If, in order to counter the demand effect, researchers cannot disclose their research hypotheses, the failure to disclose is not considered deception.

General statements about the purpose of the research, as well as a full description of the research tasks and activities, should be provided in the consent form.

Inappropriate Use of Deception

The IRB discourages the use of deception when:

- Alternative methods can be used that will yield valid study results.
- The deception deprives participants of the opportunity to protect their own interests.
- The missing information affects the participants' ability to assess the risks of participation.

Justification for Using Deception

If the subjects will be deceived, the ethical and regulatory requirement to fully inform subjects must be waived by the IRB.

There are three criteria that must be met in order for the waiver to be approved. In addition, it is usually necessary to debrief subject after the research.

- The risk must be no more than minimal.
  "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 or during the performance of routine physical or psychological examinations or tests."

- The rights and welfare of the subjects will not be adversely affected.

- The research could not practicably be carried out without the waiver. This does not mean that it would be inconvenient to conduct the study without the waiver. It means that deception is necessary to accomplish the goals of the research.

[2] The wording in this section was drawn from the Duke IRB policy on Deception in Research (https://campusirb.duke.edu/irb-policies/using-deception-research), retrieved October 10, 2019. The wording was approved by a full meeting of the Earlham IRB on October 10, 2019.

Ameliorating Deception

Protocols must include procedures for ameliorating possible negative effects of deception. In addition to thorough debriefing that explains the need for deception, emphasis should be placed on correcting any false feedback given to participants about their performance, competency, or other personal characteristics.

Participants whose behavior was recorded without their knowledge, such as during a fake "break" in study, must be given the opportunity to request that the recording be destroyed.

If a study was designed to provoke negative behaviors, participants should be told that most people react the way they reacted and that their behavior was a normal response.

Debriefing

Debriefing for participants who were deceived includes a description of the deception and an explanation about why it was necessary. The discussion should presented in lay language and should be sufficiently detailed that participants will understand how and why they were deceived. If the study included multiple deceptions, each should be addressed.

If participants were filmed without their knowledge, they must be given the option to ask that the researchers do not use the film. Data from recordings *cannot* be used unless a participant has consented.

Informed Consent

Informed consent forms and scripts may never contain deception. Researchers may not make false statements during the consent process.

Review Type for Protocols Involving Deception

Research involving deception cannot be screened for exemption.

Generally, research using the following deceptions may be reviewed using expedited procedures:

- Confederates: Attributing statements to or providing feedback from non-existent individuals or confederates in another room. Using actors in videos presented to participants.
- Giving people impersonal false information: Information about the performance of groups that participants will use to measure their own performance, for example, "Most Duke students can solve these anagrams in 3-7 minutes."
- Priming designed to focus participants' attention or awareness, but not on a sensitive topic. For example, having participants complete sentence scramble tasks with words affiliated with different goals.
- Presenting false scientific "facts," articles, or profiles of individuals or companies.
- Studies that activate stereotype threat.
- Experiments in which participants are told that two studies are unrelated when the first study is the manipulation, depending upon population and nature of manipulation.

Generally, research using the following deceptions will be reviewed by the full IRB:

- Any use of confederates in which the confederate engages in in-person dialog with a participant. For example, attempting to persuade a participant to make a certain decision or enter into a negotiation process.
- Studies in which participants are given false feedback about their own attributes, performance or abilities, for example, a manipulation in which students are told that their performance falls in the lowest quartile of Duke students following the completion of a task.
- Any study in which debriefing cannot be undertaken because to do so would cause more harm than good or when participants cannot be contacted, e.g. some types of Internet research.
- Any study involving subliminal priming.
- Covert observation and/or videotaping.
- Mood manipulations designed to induce feelings of guilt, sadness, depression.
- Any study in which participants are given false information about themselves in phase one of a study that is not corrected until a later session.
- Any deception of minors.
- Any study in which the researcher assumes a false identity.
- Manipulations designed to elicit behaviors about which participants' may feel shame or other strong negative emotions.

Researcher Rights

Individual researchers (or research groups) also have rights related to research and the IRB approval process.

- If a research project has been terminated or not approved by the IRB, the researcher has the right to appeal the decision to the IRB during a convened meeting. This is unlikely to occur, as most research not approved upon first submission is generally approved after clarification and communication between the IRB and researcher(s).

- If there are questions concerning possible violations of ethical guidelines (either on the part of the researcher(s) or on the part of the IRB), the researcher(s) and IRB committee are responsible for meeting to discuss these concerns and attempting to achieve a mutually agreeable solution.

- None of the information above should be construed to prohibit non-experimental research in field settings. If possible, permission for such research should be obtained for those in authority over the research setting. Impracticality of informed consent by those being observed and providing full clarification of the study should not rule out this type of research. Proposals of such research should still come through the IRB.

Unanticipated Problems with Research

Although every attempt should be made to prevent risks to participants, unanticipated risks can emerge on rare occasions. Because the IRB incorporates the possibility of risks into the decision-making process, no changes should be made to any research protocol except when necessary to counteract immediate hazards to a subject or subjects. In the event that any such unanticipated risk event occurs, the following steps should be taken.

Harm to a single participant

1. The research procedures involving that participant should be ended immediately, even if the research is not complete.
2. All attempts should be made to provide resources for support to rectify the harm (e.g., calling 911, phone numbers for counseling, full debriefing, etc.).
3. Within 24 hours, the IRB convener should be notified about the harm, the procedures that led to such harm, and the steps that were taken following the event.

Harm to more than one participant

1. All of the above procedures should be followed.
2. No new participants should be enrolled or involved in the research project (any enrolled participants will need to be contacted and told not to participate) and approval of the project is temporarily suspended.
3. The Principal Investigator should attend the next regularly scheduled meeting of the IRB to discuss the harms with the committee. During this meeting, the committee will deliberate the next course of action, which could be any of the following:
    a. The research project is reinstated with changes to the procedure on a temporary basis. After an agreed-upon number of participants (e.g., 5) complete any updated procedures and all other regular procedures of the original approved protocol, the Principal Investigator will meet with the IRB again to discuss the updated procedures – with a focus on participant well-being. At that point, the reinstatement with updated procedures may become permanent and subject to the original expiration date or one of the following actions will occur.
    b. The research project is terminated, but the Principal Investigator can submit a new application that addresses the problems than led to unanticipated harms.
    c. The research project is terminated and the Principal Investigator cannot submit a new proposal on the same topic.

Researchers who have multiple projects where serious unanticipated harms occur to participants will be granted IRB approvals of less than one year and will be subject to random oversight of research procedures, simply to verify that only approved procedures are being followed.

The IRB convener will report any instance of unanticipated harms to the Chief Academic Officer within 48 hours of initial notification.

Reporting Incidents to the Office of Human Research Protections

Health and Human Services (HHS) regulations at 45 CFR 46 requires Earlham College to promptly report to the Office of Human Research Protections the following:

1. any unanticipated problems involving risks to subjects or others;
2. any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB; and
3. any suspension or termination of IRB approval (45 CFR 46.108(a)(4) and 45 CFR 46.113).

The Chief Academic Officer and Office of Grants and Sponsored Research are responsible for filing the initial and any subsequent reports to the Office of Human Research Protections.

To enable prompt reporting, the IRB convener will communicate with the Chief Academic Officer and the Office of Grants and Sponsored Research within 48 hours when one of the three scenarios has occurred.

TYPES OF REVIEWS

Full Review

There are historic examples of research conducted in the United States wherein harm was done to human participants. In order to minimize harm, federal guidelines stipulate what types of research related activities require a review by the entire IRB.

Research projects requiring Full Review contain one or more of the following characteristics:

1. Study of vulnerable groups. This includes all of the groups listed under "Protected Populations" above and/or anyone who might lack the capacity for full, free, informed consent or refusal.

2. Exposure or potential exposure of the identities of participants.

3. Demonstrable or potential risk to the physical health and safety of participants greater than minimal (e.g., certain exercise protocols, ingestion of substances not proven to be wholesome, encroachment on a subject's bodily boundaries).

4. Risk of emotional distress (e.g., invasive questioning on sensitive issues).

5. Potential loss of livelihood (e.g., interviewing a subject regarding their work environment).

6. Use of deception (e.g., giving participants false feedback about their scores on a personality test). Not all studies using deception need full review. Please consult the "Using Deception in Research" section.

7. Research going beyond strictly classroom pedagogical purposes that will be presented to the wider public (e.g., at a conference or in a publication) that might expose participants' identities, regardless of whether they have consented to the risk of identity exposure.

8. Risk of criminal or legal liability for the subject (e.g., asking questions about stealing).

9. Research conducted in non-US locations (e.g., research conducted while on a study abroad program).

Again, if **any** of the above conditions are met, a full review must be conducted. Please download and complete the form titled "EC-IRB_FullReview." In addition to this document, ALL research-related materials must be included for IRB review.

When conducting research outside of the United States, we need to follow the guidelines of the U.S. and the country in which the research will occur. Because researchers are affiliated with Earlham College, the Earlham College IRB reviews and approves research even when it is conducted internationally. However, additional information is needed, such as whether there are any research guidelines for the specific location where the research will take place. The U.S. Office for Health and Human Services has compiled a listing of guidelines for many other countries; this compilation can be downloaded in Word of PDF format at the following url: https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html.

Research projects and protocols approved via Full Review are approved for one year from the date of the approval notification. If the research is to continue after one year, a Change/Continuation form (see below) or another review is required *before* the expiration of approval.

Finally, research projects approved via Full Review that are considered by the IRB to have a high degree of risk will be visited randomly by an IRB member to verify that no material changes have been made since IRB approval.

Expedited Review

Research projects that present minimal or no risk to human participants, which covers most of the research conducted on Earlham's campus, may be submitted to the IRB for an Expedited Review. An Expedited Review does not need to be deliberated on at a convened meeting. Instead, approval will involve two members of the IRB committee. It is up to the discretion of the IRB if Expedited Review proposals have an expiration date.

Research submitted for an Expedited Review cannot be used for research where subjects could be harmed if identified, unless reasonable protections are in place to prevent participant identification. In addition, all informed consent requirements are in place for research approved via Expedited Review.

In order to submit a project for Expedited Review, **all** research procedures must fit within the federally-approved categories below (see www.hhs.gov/ohrp/policy/expedited98.html).

1. You are collecting blood samples by finger, heel, or ear stick from healthy, non-pregnant adults weighting at least 110 pounds or from other adults and children as long as the following requirements are met: no more than 2 blood collections per week over a period of not more than 8 weeks, where blood drawn is less than 50 ml per kg of body weight in adults or less than 3 ml per kg of body weight in children.

2. You are collecting biological specimens for research in a non-invasive ways, such as non-disfiguring hair or nail clippings, sweat collection, saliva collections of unstimulated or stimulated forms (e.g., by chewing gum base), skin cells collected via buccal scraping, or other similar non-invasive ways.

3. You are collecting data using non-invasive, regularly employed clinical means, such as external sensors, sensory acuity testing, strength-testing, or other means, but excluding x-rays or microwaves.

4. You are engaged in research on materials that were not collected solely for research purposes, such as medical treatments. (Some of this research may be exempt from IRB review, see below.)

5. You are collecting data from a preexisting recording made for research purposes, including voice, video, digital, or image recordings.

6. You are collecting data on individual or group behaviors/characteristics, such as research about perception, attitudes, identity, language, etc., using surveys, interviews, focus groups, or other methodologies. (Some of this research may be exempt from IRB review, see below.)

Remember that all research for Expedited review must be of minimal or no risk. Otherwise, even research falling within these categories is subject to a Full Review. Please download and complete the form titled "EC-IRB_Expedited." In addition to this form, an informed consent document and other relevant materials must be submitted for IRB review.

Exemption from Review Request

Research that has no risk to the participants and does not include vulnerable populations may be exempt from IRB review. However, individual investigators are not allowed to make this determination, so a brief form ("EC-IRB_Exemption," downloadable from the IRB website) for any research that may be exempt should be submitted to the IRB.

In order to be considered exempt from IRB review, **every part** of the research project must fall under one of the Exempt types of research. Even so, some types of approved Exempt research may still require informed consent from participants (e.g., anonymous surveys using online participant pools); in such cases, researchers should submit a consent document to the IRB.

Based on the federal guidelines for research exempt from Full Review, you may apply for an Exemption if:

1. You are investigating normal educational practices, such as a comparison of curricula or classroom management methods in an established educational setting.

2. The project uses observational, survey, interview (oral history), or educational (cognitive, diagnostic, aptitude, achievement) testing procedures, if one of the following is true:
    a. Participant identities are anonymous or cannot be easily determined through description or linked identifiers.
    b. Any disclosure of identity would not lead to criminal liability or damage to participants' employment, financial standing, education, or reputation.
    c. The IRB approves the disclosure of participant identities.

3. You are doing research using benign behavioral interventions paired with data collection, if one of the following is true:
    a. Participant identities are anonymous or cannot be easily determined through description or linked identifiers.
    b. Any disclosure of identity would not lead to criminal liability or damage to participants' employment, financial standing, education, or reputation.
    c. The IRB approves the disclosure of participant identities.

4. The project is secondary research that involves studying existing data, recordings, or other documents, if any of the following are true:
    a. Participant identities and specimens are publically available.
    b. Identities are stripped and not labeled in a way that can lead to identification.
    c. Research focuses on federally mandated analysis of health data.

5. Your project is supported by the federal government/agency and focuses on evaluation of public benefit programs and is approved by the organization being studied, if relevant.

6. The project is on customer perception of taste and food quality using only FDA approved wholesome foods or includes products at or below levels found safe by various federal agencies (e.g., FDA).

7. Storage of identifiable data/biospecimens for secondary research when broad consent was obtained from participants.

8. Secondary research on stored identifiable data/biospecimens, if ALL of the following are true:
    a. Broad consent was given by participants at the time of data collection.
    b. There is documentation of informed consent.
    c. The IRB does a minimal review to ensure participant identities are secure.

Research projects and protocols that are exempted from review do not need to be re-approved *unless* any changes are going to occur. Changes in population, research methods, questions, etc., will all need to be submitted to the IRB via a Change/Continuation form or via a new proposal. Studies using deception are not eligible for Exempt review.

Change to or Continuation of Previously Approved Research

In cases where small changes need to be made to an approved research protocol, researchers must complete and submit a Change/Continuation form (downloadable from the IRB website). In all cases, it is possible that the IRB convener will request a new review based on any proposed changes.

Research Proposals with an Expiration Date

- Only one Change/Continuation form may be submitted per approved research protocol. Afterwards, a new proposal must be submitted.
- A Change/Continuation form must be submitted before the expiration date of the initial approval has passed. If the expiration date has passed, a new proposal will be required.
- Approval of a Change/Continuation will change the expiration date of the original approval to one year after the approval of the Change/Continuation.

Research Proposals without an Expiration Date

- Only two Change/Continuation forms may be submitted per approved research protocol. Afterwards, a new proposal must be submitted.
- Approval of a Change/Continuation may or may not lead to an expiration date for the updated research. If an expiration date is added, that expiration date applies to the entire research protocol, not simply the changed elements.

Below are the types of adjustments that may be submitted via a Change/Continuation form.

1. Minor changes to research protocols that were previously approved. Submitting this type of change means that data collection must be stopped until the changes are approved or may continue only under the previously approved protocol. Some examples include:
    a. The addition or removal of questions asked of participants;
    b. Recruiting/data collection from a new population source; and/or,
    c. Increasing the number of participants to be involved.
2. Continuation of research previously approved. This type of change request will be most common for research proposals with an expiration date. Some examples of research continuation include:
    a. No changes are being requested aside from an extension of an expiration date for an approved research protocol; and/or,
    b. Research is closed to new participants and all enrolled participants have completed research-related activities, but long-term follow-up with existing participants is desired.

Other types of changes may also be considered.

PROCEDURES

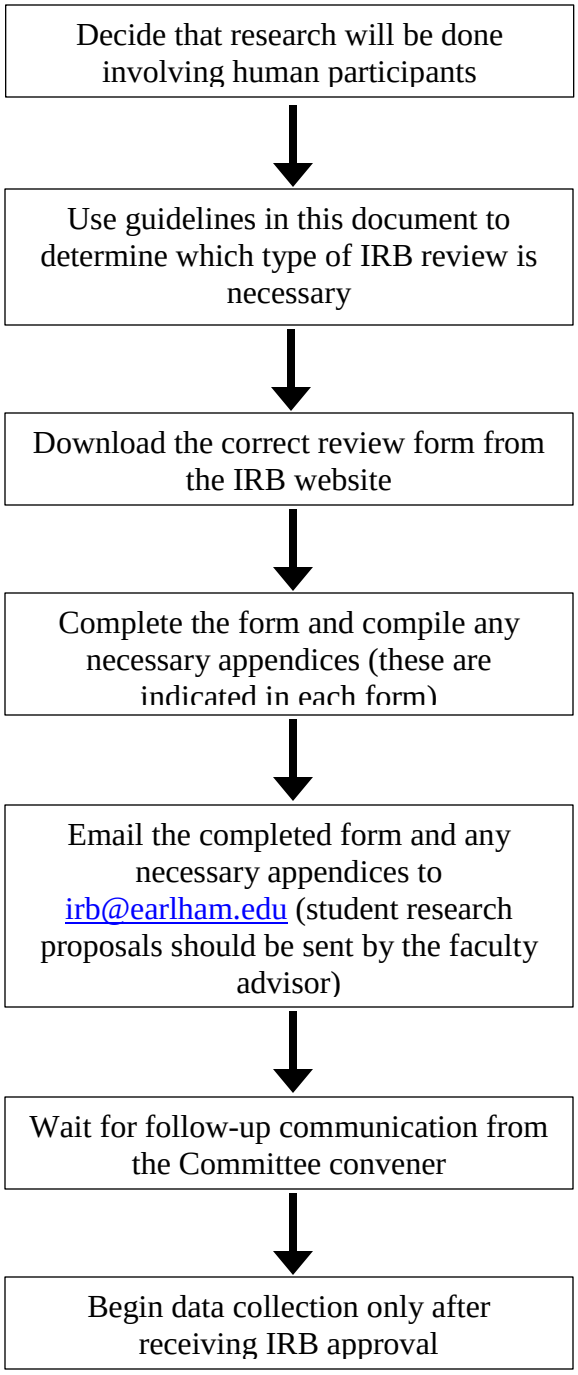
IRB Proposal Review/Approval Process

This is the general process for application approvals.

1. An application is submitted to the email address irb@earlham.edu. This is forwarded to the Convener's email.
2. The Convener numbers the application, saves it to the shared IRB groups folder (accessible only by IRB members), and adds the pertinent information to the IRB tracking document.
3. The Convener sends an email notification about a new proposal to be reviewed.
    a. Depending on the type of review required, this email may go to two members of the committee or the entirety of the committee.
4. Committee members read the proposal.
    a. For Full Proposals, committee members should bring questions, concerns, and/or decisions to the scheduled meeting.
    b. For all other proposals, committee members should reply-all with approval, questions, or disapproval to the Convener and other reviewer.
5. The decision on any proposal is passed on to the Principal Investigator.
    a. If the request is approved, the proposal is amended to include approval information and is converted to PDF to return to the PI. All approved protocols are stored in the appropriate folder in the shared IRB folder in the groups drive.
    b. If committee members have questions about the proposal, the Convener does nothing with the request, but relays any questions (without attaching names of the questioners) to the PI.
        i. For Full Reviews, the PI's answer must be provided before the next regularly scheduled meeting so that it can be discussed by the IRB before further decisions can be made.
        ii. For all other reviews, PI answers will be distributed to the original reviewers via email before further decisions can be made.
    c. If the request is not approved, the IRB is returned to the PI with a notification of non-approval and the reason for the non-approval.

Full review research protocols are good for one year from the notification of approval. All other approvals are approved indefinitely in their submitted state unless an expiration date is requested by the IRB. Such expirations will be noted on the approved document.

Review Procedures Flowchart



Review Procedure Specifics

Full Review

A Full Review needs to be discussed and approved at a committee meeting that occurs in person. The researcher (or Faculty sponsor) sends the completed document, along with all materials (questions, pictures, procedures, informed consent, etc.) to the convener (irb@earlham.edu). Committee members read the application prior to the meeting. Full Review applications must be received more than 4 business days before a meeting in order to be discussed at the next scheduled meeting. Any applications coming less than 4 days before a meeting will be discussed at the subsequent scheduled meeting. Full Review applications can only be voted on, and thus approved, if attendance at the meeting meets the federal definitions of a quorum. The federal guidelines define quorum for an IRB meeting as more than half of the members present, including at least one committee member who is considered a non-scientist. If either of these criteria are not met, quorum is not achieved.

Expedited Approval

An Expedited Approval is generally approved by two members of the committee, although the convener may approve the proposal alone when necessary for expediency. The researcher (or Faculty sponsor) sends the completed document, along with all materials (questions, pictures, procedures, informed consent, etc.) to the convener (irb@earlham.edu), who assigns it to two committee members to review. Committee members will read the document and send their assessment (either approval or points of clarification/concern) to the convener no more than 3 business days after the proposal is assigned. These proposals will be equally divided among non-student committee members as much as possible, with the caveat that no proposal will be reviewed by student members exclusively.

Exemption Request

An Exemption Request is generally approved by two members of the committee, although the convener may approve the proposal alone when necessary for expediency. The researcher (or Faculty Sponsor) sends the completed document and any necessary additional documents to the convener (irb@earlham.edu), who assigns it to two committee members to review. Committee members will read the document and send their assessment (either approval or points of clarification/concern) to the convener no more than 3 business days after the proposal is assigned. These proposals will be equally divided among non-student committee members as much as possible, with the caveat that no proposal will be reviewed by student members exclusively.

Change/Continuation of Previously Approved Research

Change/Continuations will be approved in the same manner as the original proposal (e.g., changes to a Full Review will go before the entire committee, whereas changes to an Expedited Review or Exemption will go only to the original reviewers, when at all possible). The researcher (or Faculty sponsor) sends the completed Change/Continuation document to the convener. Ideally, the researcher/faculty member should hear something about a Change/Continuation request (either approval or request for clarification) no more than 3 business days after it is submitted or after the next scheduled meeting of the IRB, depending on the type of proposal.

Review of Research Approved Elsewhere

The updated Federal guidelines require that a single IRB be engaged in oversight of a research program, even if that program occurs at multiple locations with unique IRBs. Thus, researchers with research protocols approved by other IRBs who wish to collect data on Earlham's campus or with Earlham community members must send an email to the IRB convener at irb@earlham.edu.

The body of the email must have the following information:

- researcher name, institutional/organizational affiliation, and contact information;
- the name of an Earlham community faculty or staff member who has agreed to allow research within their constituency on campus and be an on-campus contact for the research program; and,
- a brief summary of the research topic, procedures, time frame, modes of contact, and any compensation.

Attached to the email must be proof of IRB approval.

All other guidelines for research on campus must also be followed.

IRB Reports

The IRB will generate reports covering IRB activities for each school year (running from July 1st through June 30th of the following year). These reports will be completed within one month of the end of the year of coverage and will be provided to the President, Chief Academic Officer, and greater Earlham community. All reports will be available for public view via contacting the IRB convener.

Reports will contain the following:

- The number of approved projects, which will also be broken down in the following ways:
    - The number of approvals by type
    - The number of approvals by division
    - The number of approvals by academic department
- The number of projects that encountered unanticipated problems
- The number of projects that were suspended or terminated by the IRB

FOR COMMITTEE MEMBERS

Required Training

To maintain our Federalwide Assurance, the IRB convener and Chief Academic Officer must complete the Human Subject Assurance Training provided by the Office for Human Research Protections requires completion of the training modules at the following website: https://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp.

- The IRB convener must complete all three modules. The convener should also complete items 2 and 3 below.
- The Chief Academic Officer (aka Institutional Official) must complete the first module.

Upon becoming a member of the IRB, new members must complete the following activities:

1. An online research ethics training module via the National Institute of Health. This online training module explains some elements of research history that necessitate the oversight of IRBs, as well as provides overviews of major concerns surrounding the use of human participants, such as vulnerable populations (e.g., children) or deception. Successful completion of this online training module results in a certificate. All IRB members must have their completion certificates on file. This training module can be found at the following url: http://phrp.nihtraining.com/users/login.php.
2. Reading the Belmont Report. The Belmont Report, published by a special governmental commission in 1979, outlines the guiding principles for treating human subjects of research with respect.
3. Reading Yeater, Miller, Rinehart, & Nasson (2012). This article investigates college students' perceptions of and reactions to research focused on issues of trauma and/or sex. Given that many of the students doing research on campus may be interested in this topic, the results of this article could inform our work.

IRB Numbering System

All IRB proposals will be numbered as soon as they are submitted to the convener. These numbers, as well as information about the name of the researcher(s), the type of IRB request, the date submitted, etc., will be entered into the IRB Tracking Excel document located in the shared folder in the groups drive.

IRB requests should be numbered as follows:

- Full request = four-digit school year *dash* f three-digit code (e.g., 1314-f021)
- Expedited request = four-digit school year *dash* e three-digit code (e.g., 1314-e064)
- Exempt request = four-digit school year *dash* x thee-digit code (e.g., 1314-x114)
- Change/Continuation = original IRB number *dash* ch current four-year school year (e.g., 1718-e027-ch1819)
- Protocols approved from off-campus IRBs = four-digit school year *dash* i three-digit code (e.g., 1314-i001)

Within each type of approval, the three-digit code should be the next available number.

REFERENCES

Feige, M. (2014, May). *The Nuts and Bolts of 45 CFR part 46: The HHS Regulatory Basics.* Talk presented at "Clinical Research and All That Regulatory Jazz" OHRP Research Community Forum, Cincinnati, OH.

Koppelman, E. (2006). *Explanation of Federal Regulations for human subjects research, part 1.* Retrieved from Online Ethics Center for Engineering, National Academy of Engineering website: http://www.onlineethics.org/Resources/TeachingTools/20357/19237/resethpages/reghum.aspx

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