Guidelines and Procedures for
Research Using Human Subjects

Earlham College IRB

Revised Summer 2015
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OVERVIEW

Both faculty and students at Earlham College, the Earlham School of Religion, and the Master of the Arts of Teaching and Master’s in Education programs conduct research on human subjects. Such research is regulated by federal guidelines to ensure that the rights of every human subject are protected. 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), the IRB consists of at least five voting members. Earlham’s IRB is comprised of at least four Earlham faculty members with expertise across the liberal arts disciplines and at least one reviewer from outside of the College. The IRB is under the oversight of the Academic Dean 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 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 or a subset of IRB members.

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.
COMMITTEE MEMBERSHIP

The responsibility of the members of Earlham’s IRB is to make sure that all research 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 physical, emotional, and psychological well-being. All research involving human participants must come through the IRB for approval (or for approval of exemption from IRB review, see below). 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.

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 is as follows:

Convener
Margaret Thomas, Assistant Professor of Experimental Social Psychology, Earlham College

Members
Polly Albright, Associate Director of Institutional Research and Assessment, Earlham College
Cathryn Dickman, Director of Wellness Programs, Earlham College
Kendal Harris, Pastor, Bethesda Worship Center
Selina Hardt, Student, Earlham College
Lara Kalifeh, Student, Earlham College
Tim McLarnan, Professor of Mathematics, Earlham College
Ryan Murphy, Assistant Professor of History, Earlham College
Maxwell Paule, Assistant Professor of Ancient and Classical Studies, Earlham College
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 from living human individuals via interaction (even if not face-to-face) or intervention
- **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
- **Deception**: deliberately mis-informing participants about the nature of the research (e.g., providing false feedback about performance on an exam, providing a different topic of research than the actual topic, etc.). Deception should NOT be taken to mean 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”).
FOR RESEARCHERS

IMPORTANT INFORMATION

• The IRB approves research proposals for one year from the date of notification of approval.
• Only the exact procedure and materials approved 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.
• 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 a required ethics training module. This 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 a score of 70% or better is required to successfully complete the training module. No research will be reviewed, much less approved, unless all individuals named on an IRB proposal have passed the quiz associated with the training module. 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 an example of an informed consent document that can be downloaded from the IRB’s webpage. 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. In general, all of the following information must be included.

1. Researchers must inform participants of all features of the research that might be expected to influence willingness 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, there must be an explanation of any alternative treatments that are available.

2. Researchers must inform participants about any possible physical or 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 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).

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; 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 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. Should 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 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 broad informed consent document, 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, that recording occurred must be divulged to research participants at the end of their involvement in the research. Then, 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. 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 the populations below 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.

- **Pregnant women, fetuses, and neonates.** Federal guidelines for research involving pregnant women and fetuses focus on the well-being of the woman and/or fetus, specifically surrounding risk to health or viability. In general, research using these populations should only be for the benefit of the participants or to society at large, and should only be carried out if no other usable alternatives are available.

- **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 board cannot be associated with the prison from where the population will be sampled.

- **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.
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 in 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 processes 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, 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 involved (e.g., 5) wherein all regular procedures surrounding unanticipated harms are in place, the Principal Investigator will meet with the IRB again. At that point, the reinstatement will 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 Academic Dean within 48 hours of initial notification.
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 children under age 18 (parental permission must be secured), prisoners, people with developmental disabilities, illegal immigrants, members of politically disadvantaged groups, and 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).

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: http://www.hhs.gov/ohrp/international/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 (Full or Expedited, see below) 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 often takes less time than a Full Review and will involve two members of the IRB committee, rather than the full committee, and does not need to be deliberated on at a convened meeting.

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](http://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, oral histories, 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 Exempted.” 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); 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. You are carrying out observational research in a public place in which you are not participating (e.g., a local park). Federal policy covers only research on human subjects in which the information collected is private. Private refers to behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and to information a subject may divulge which they can reasonably expect will not be made public.

3. You are administering an anonymous survey. Surveys using Earlham students where more than one piece of demographic data is collected may not fit here, as individual identities could be figured out after data collection.

4. You are interviewing people who are professionals or experts in some area and you are only asking them questions that focus on their areas of expertise. If you ask a political, artistic, academic, or other kind of expert personal questions outside her/his area of expertise, this research is not exempt.

5. The project involves studying existing data, recordings, or other documents, and any identities are still protected/anonymous.

6. Your project focuses on evaluation of public benefit programs and is approved by the organization being studied, if relevant.

7. The project is on customer perception of taste and food quality using only FDA approved wholesome foods.

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.
Change/Continuation of Previously Approved Research

In cases where small changes need to be made to an approved research protocol during the year of approval, 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 Full or Expedited Review based on any proposed changes.

Approval of a Change/Continuation for a research protocol will change the expiration date of the original approval to one year after the approval of a Change/Continuation. However, only one Change/Continuation form may be submitted per approved IRB. Afterwards, a new proposal must be submitted.

Only the following types of research activities may be submitted via a Change/Continuation form.

1. **Minor changes to research previously approved within one year of the original approval date.** Since research projects and protocols are approved for one year, changes that need to be made during that year must also be approved. Submitting this type of review means that data collection must be stopped until the changes are approved or may continue only under the previously approved protocol.

2. **Continuation of research previously approved.** One year from the notification of approval, researchers are no longer allowed to enroll new participants. However, if any of the following conditions are met, researchers may submit a Change/Continuation form.
   a. Research is closed to new participants and all enrolled participants have completed research-related activities, but long-term follow-up with participants is desired.
   b. No participants enrolled or participated in the research during the year of approval and no new risks have been identified.
   c. Research qualified as having minimal or no risk to participants (e.g., approved via Exemption or Expedited Request), no changes have been made to the research protocol(s), and it is necessary or desirable to enroll more participants. Researchers must explain why it is necessary to enroll more participants.
   d. Remaining activities are limited to data analysis.

3. **Gathering data from recordings (voice, video, digital, image) made in the course of approved research during the year of approval.** If the initial approved protocol included any type of recordings, more information can be gathered from those recordings after the initial year of approval via Change/Continuation form.
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 respond with approval, questions, or disapproval to the Convener.

5. The decision on any proposal is passed on 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.

Approved research protocols are good for one year from the notification of approval, with the exceptions of Exemption proposals, which are approved indefinitely in their submitted state. Unless a Change/Continuation Form is completed and approved, after eleven months, an IRB representative will send a follow-up email to the PI. This email will include the IRB number, project title, and expiration date, along with a few questions for the PI to answer. PIs who do not respond to this email will not have another proposal approved.
Review Procedures Flowchart

1. Decide that research will be done involving human participants.
2. Use guidelines in this document to determine which type of IRB review is necessary.
3. Download the correct review form from the IRB website.
4. Complete the form and compile any necessary appendices (these are indicated in each form).
5. Email the completed form and any necessary appendices to irb@earlham.edu (student research proposals should be sent by the faculty advisor).
6. Wait for follow-up communication from the Committee convener.
7. Begin data collection only after receiving IRB approval.
8. Respond to email sent after 11 months of approval.
Review Procedure Specifics

Full Review
A Full Review needs to be discussed and approved at a committee meeting that occurs in person. The researcher sends the completed document, along with all materials (questions, pictures, procedures, informed consent, etc.) to the convener. Committee members read the application prior to the meeting. Full Review applications must be received more than 4 days (96 hours) 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 needs to be approved by two members of the committee. The researcher sends the completed document to the convener, 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 needs to be approved by two members of the committee. The researcher sends the completed document to the convener, 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 sends the completed 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.
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, Academic Dean, and greater Earlham community. All reports will be available for public view via contacting the IRB convener.

• The number of approved projects, which will also be broken down in the following ways:
  o The number of approvals by type
  o The number of approvals by division
  o 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

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](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 followed by CC (e.g., 1314-F003CC)

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

