*Note: This section is being revised. Please contact the Office of Sponsored Programs and Research for the most up-to-date information.*

# *F7.1 Human Subjects Review Committee (IRB)*

## F7.1.1 Introduction

The major goal of East Central University is to serve the larger community of the state of Oklahoma by providing opportunities for higher education to students as well as broadening the horizons of research. In so doing, the rights and privacy of all people concerned must be protected. The university willingly undertakes this responsibility, while at the same time endeavoring to not infringe upon the academic freedom of the members of the university. As part of this responsibility, the university seeks to protect the rights of individuals involved as subjects in research projects.

## F7.1.2 Federal Regulations

The East Central University (ECU) Institutional Review Board (IRB) is governed by the Code of Federal Regulations 45 CFR 46 to protect the rights and privacy of human research subjects. CFR 46.F73(a) requires that institutions conducting research supported by any federal department or agency file an assurance with the United States Department of Health and Human Services (HHS). The university acts in accordance with the Office for Human Research Protections' (OHRP) Terms of Assurance under Federalwide Assurance # FWA00013984.

ECU's ethical principles regarding human research are also guided by the "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research" of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. These principles are applicable when human subjects are involved in research regardless of funding sources

## F7.1.3 Committee Structure

The Institutional Review Board (IRB) shall consist of six (6) members, one of which must be a non-scientist; five (5) shall be the current members of the Research and Professional Development Committee. The sixth person, who shall be appointed by the vice President for academic affairs, shall not be affiliated with ECU and shall not a part of an immediate family of a person affiliated with the institution. All members shall have sufficient experience and expertise to provide professional advice and counsel related to the protection of human subjects in research.

The IRB Chair and the administrative liaison will review all research activities involving human subjects and determine the level of review. Any member, who has a conflict of interest with the initial proposal or renewal under review, shall not participate. However, they may provide information requested by other members of the committee. The IRB will notify investigators of any findings or actions conducted in the review process.

## F7.1.4 Educational Requirement

The Office for Human Research Protections (OHRP) of the Department of Health and Human Services strongly encourages institutions to develop educational training for all IRB members and those investigators that will be involved in human subject research. OHRP recommends that IRB members complete appropriate educational training prior to reviewing human subject research as established by the Office of Sponsored Programs and Research (OSPR). Investigators must complete their training prior to submitting application to the IRB for any human research activities.

All ECU investigators, research staff, and key personnel involved in human subject research must complete the initial training at the National Institutes of Health Protection of Human Subject Research educational course at https://phrptraining.com. Upon completion of the training, print and submit the Certification of Completion along with the IRB application. Supervising faculty shall certify that research students have knowledge and demonstrate competency of topics and issues related to human subject research.

## F7.1.5 Refresher Course

IRB members, investigators, research staff and key personnel are required to complete a refresher course every three (3) years at https://phrptraining.com.

## F7.1.6 Applications for IRB Review

All members of East Central University (undergraduate and graduate students, faculty, and administrators) who intend to do research employing human subjects, as well as non-university members wishing to conduct research using any members of East Central University, must file a full proposal with the IRB.

The IRB's approval of a research project shall be contingent on the following:

1. Sufficient information will be provided to potential subjects to enable them to make an informed decision, including, but not limited to, an explanation of the purposes of the research and a description of any reasonably foreseeable risks or discomforts,
2. Assurance that any potential risks will be minimized and are reasonably proportional to the expected benefits, and
3. Provision of reasonable estimates of time involved in the study and number of participants.

It is the ultimate responsibility of the individual researcher to file their proposal with the IRB. Students engaging in research with human subjects are responsible for filing their proposals; however, it is the duty of the supervising faculty member to inform students of their responsibility and to review their student's proposal before submission to the Board.

To ensure application review in a timely manner, IRB proposals shall be filed thirty (30) days prior to the proposed start date of the research. (Exception: Applications requesting exempt or expedited status may be filed within fifteen (15) days prior to the proposed start date.) Failure to file proposals and obtain approval prior to administering any research instrument involving human subjects is in violation of Code of Federal Regulations 45 CFR 46 and ECU policy. Noncompliance with the policy and guidelines may result in disciplinary action. Investigator(s) conducting research that is not in accordance to this policy must accept full responsibility for the consequences of their research activities.

The original signed application should be sent to the Office of Sponsored Programs and Research at room 226 of Danley Hall and emailed to IRB@ecok.edu.

## F7.1.7 Application Form

APPLICATION TO THE INSTITUTIONAL REVIEW BOARD

The IRB application, IRB related forms and the IRB policy can be found at the East Central University Office of Sponsored Programs and Research website.

## F7.1.8 Types of IRB Review

**Exempt:**

IRB may consider an application exempt if the following criteria are met (45 CFR 46.F71):

1. the research involves at least one of the following:
    - the collection or study of existing unidentifiable data, documents, records, pathological specimens, or diagnostic specimens
    - the use of educational tests, survey procedures, interview procedures, or observation of public behavior,
    - the use of commonly accepted educational settings, involving normal educational practices
2. The subjects involved cannot be directly or indirectly identified, and
3. Disclosure of the subjects' information cannot place them at risk for criminal or civil liability or be damaging to their financial standing, employability, or reputation.

**Expedited Review:** http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm

According to 45 CFR 46.1F7, IRB may review research in an expedited process for the following:

1. Research involving no more than minimal risk to research subjects and others, and/or
2. Research involving minor changes to the previously approved research during the project period (of one (1) year or less) for which approval was authorized.
3. The subjects involved cannot be directly or indirectly identified, and
4. Disclosure of the subjects' information cannot place them at risk for criminal or civil liability or be damaging to their financial standing, employability, or reputation.

**Full Review**: Application is subject to full IRB review if it meets any of the following:

1. The research involves more than minimal risk to research subjects and others,
    - The research involves public official(s) or candidate(s) for public office,
    - Subjects' personal information can be identified directly or indirectly (through a naming system).
2. Disclosure of the subjects' information may place them at risk for criminal or civil liability or be damaging to their financial standing, employability, or reputation.

**Minimal risk:** "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 the performance of routine physical, psychological examinations or tests" (45 CFR 46.F72{i}).

## F7.1.9 Consent Forms

Unless waived by the IRB, investigators shall not to employ human research until the subjects (or their legal representative) have given their consent.

The informed consent shall follow the guidelines listed below:

1. It shall contain information explaining the nature of the research, the risks and benefits, the expected duration of the research, and the number of expected participants.
2. The subject (or their legal authorized representative) shall sign the consent form before participation is allowed.
3. The language contained within the form must not be exculpatory.
4. It shall consist of a statement informing the subjects that their participation is voluntary and free of coercion or undue influence.
5. It shall consist of a statement guaranteeing subject information confidentiality.
6. It shall consist of a statement informing the subjects that their refusal or withdrawal to participate will not result in penalty or loss of benefits to which the subject is otherwise entitled.
7. It shall consist of a statement informing the subjects that the investigator may terminate their participation at any given time without prior notice.
8. It shall list the name(s) and number(s) of a contact person(s) for participants to call for further questions or concerns regarding the research and their rights.

The informed consent must be provided by the investigator and approved by the IRB prior to use.

## F7.1.10 Changes to the Initial Application

Investigators are required to notify the IRB of any changes to the initial approved proposal. The Board must approve modification(s) prior to the start of the research. The sponsoring department or agency will grant the final approval.

## F7.1.11 Change in Initial Status of Human Subject Research

Proposals that did not initially incorporate human studies must inform the IRB and the sponsoring department or agency of the change in human research activities. Immediately after the investigator(s) identifies that the research will involve human subjects within the period of support, they must file an application with the IRB for approval. The certification will be submitted to the department or agency by the institution. However, the sponsoring department or agency shall have the final approval for the proposed change.

## F7.1.12 Unanticipated Harm and Non-compliance Report

To protect the welfare of research subjects, the investigator(s) shall immediately notify the IRB of any unforeseen injuries or harm to the research subjects or others. Those that are not in compliance with the institution's IRB policy shall be reported to the committee. Appropriate action will ensue.

## F7.1.13 Continuing Review and Final Report

Continuing application shall be renewed annually and submitted thirty (30) days prior to the expiration date to ensure approval in a timely manner.

A final report shall be submitted to the IRB no later than thirty (30) days upon the completion of the study.

## F7.1.14 Suspension or Termination of IRB Approved Research

In the case of a termination or suspension of the human research project, the committee shall issue a written statement to the investigator stating the reasons for the action.

## F7.1.15 Retention of IRB Records

East Central University shall retain IRB records for five (5) years beyond the end of the completion of the study. They will include all records related to the project, but not limited to, reviewed research proposals, scientific evaluations, approved samples of consent documents (if applicable), copies of correspondence between the committee and the investigators, progress reports, and reports of injuries to subjects.

In addition, records of IRB meetings shall be retained for five (5) years beyond the end of the completion of the study. They will include all records related to the project, but not limited to, details of the minutes of the IRB meetings, attendance, actions taken by the IRB, the voting outcome of the application approval or disapproval, reason(s) for the action, suggestions and comments for modification if disapproved, and a written summary of opposed issues and resolution discussed.

## F7.1.16 Questions and Answers

Please contact the IRB committee with any questions at IRB@ecok.edu.

## F7.1.17 Links to Additional Resources

1. Code of Federal Regulations Title 45, Part 46
2. The Belmont Report - Ethical Codes and Regulations for Human Subjects in Research
3. Office for Human Research Protections (OHRP)