

Title : Human Subjects Research Review Procedure
Number :
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All external parties that are conducting research on Eastern Arizona College employees or students are required to have their projects reviewed by Institutional Research, prior to proceeding. Students and employees of the College are asked to contact Institutional Research to determine what process, if any, is required before conducting the research project.

Some projects may be exempt from review if they are conducted by Eastern Arizona College instructors or students in their classes or by departmental personnel within their own department AND if the data collected, does not contain personally identifiable information.

Eastern Arizona College's Human Subjects Review Committee (HSRC) is responsible for evaluating potential research projects to ensure that risks to any party are limited and they are in compliance with standards outlined by the Code of Federal Regulations, Title 45 (45 CFR Part 46) Protection of Human Subjects.

Review Procedure

The review process is designed to protect the rights and welfare of human subjects by ensuring equitable subject selection, assuring adequate informed consent, assessing and minimizing risks, and maintaining privacy and confidentiality. The process begins with Institutional Research determining the potential risk level, defined below. If the project is determined to pose no risk, a formal application is not required; however, researchers not affiliated with the college are still required to obtain permission to proceed and subsequently submit a follow-up report for all studies.

I. Determine the Research Project's Risk Level

Institutional Research determines the risk level for every research project. If the risk level is "no risk" or "minimal risk" an expedited approval process can be used. The risk level definitions are as follows:

- **No Risk**: Research projects that are perceived to have no risk are not required to undergo a formal review. Surveys/research projects that do not elicit information of a personal nature from respondents are considered "no risk". Examples of projects that are determined to have no risk include in-class surveys, student projects that involve no outside subjects, faculty surveys of their own students, and similar projects.
- **Minimal Risk**: Research projects are considered minimal risk when they exceed the no risk level but still pose little risk to the subjects. These projects will be reviewed and approved by Institutional Research. Examples of projects that are determined to have minimal risk include surveys, interviews, oral histories, focus groups, or program evaluations where no personally-identifiable information is gathered.
- **Moderate to Substantial Risk**: Research projects deemed by Institutional Research to have moderate to substantial risk to human subjects will be assigned to the HSRC for resolution. Examples of projects in this category include studies with vulnerable populations, studies that employ deception, international studies, and studies where information may be disclosed that could require mandatory legal reporting or elicit personally identifiable information.

II. Submit Application for moderate to substantial risk:

Applications and all materials must be submitted before evaluation of the research project can begin. Applications should be submitted to Institutional Research at least one month prior to the anticipated project



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start date. Forms are available on Knowledgebase, the Institutional Research webpage, and through the Institutional Research Office.

III. Decision-making and Official Response from HSRC

The Human Subjects Review Committee will review all complete applications and make a decision, along with appropriate recommendations for the research project. The project leader will receive a formal recommendation within one-month of the application submission for projects deemed to be moderate to substantial risk and will receive expedited approval for those falling in lower risk categories.

Decisions made by the HSRC can be appealed. To appeal a decision, the applicant must submit a completed appeal form within ten business days of receiving the decision. After review, the HSRC will communicate its decision to the applicant. If desired, a second appeal may be made to the Vice President of Operations. The Vice President of Operations will then communicate the final decision to the applicant.

Human Subjects Review Committee

The Human Subjects Review Committee (HSRC) will maintain fairness and impartiality in its review process and will be comprised of at least five members, diversified by race, gender, cultural background, and profession. The HSRC will be chaired by the head of Institutional Research and will include at least one member from a scientific area, one from a non-scientific area, and one person not affiliated with Eastern Arizona College who is knowledgeable about the local community. The committee will be convened on an as needed basis.

Procedures for Continuing Review of Projects

Human subjects research approval is valid for one year or for a shorter interval determined by the HSRC based on the risks involved. If the research continues beyond a year, a Periodic Review Form must be submitted to extend approval for the next year.

In addition to the routine periodic review, researchers are obligated to keep the Institutional Research Office informed of unexpected findings involving risks and to report any occurrence of serious harm to subjects. Problems of these types must be reported without delay. Failure to comply with the periodic review requirements, or failure to immediately report problems involving risk to human subjects not foreseen in the approved protocol, will be cause for suspension or termination of the study. To the extent that the study is an integral part of any funded research project, the project scope may need to be formally altered should a study be terminated or suspended. This suspension notice will be reported to the researcher, institutional officials and external funding sources.

Changes in Research Design

Any proposed change, amendment, or addendum to a protocol or consent form must be reviewed and approved by Institutional Research prior to implementation. The researcher is required to provide a letter to Institutional Research describing the change, amendment, or addendum including:

- 1) any proposed changes in the procedure/study design,
- 2) any change in risk and/or benefit to the subjects
- 3) any/all revisions necessary to the consent form.



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The Institutional Research Office has the responsibility for judging whether or not a proposed change, amendment, or addendum will increase the subject risk, and has the authority to approve proposed changes that do not involve increased risk. Changes, which substantially increase risk, must be approved by the HSRC.

Data Management

The researcher is solely responsible to assure privacy and confidentiality to all research subjects and must provide processes to protect all data gathered. The following represents reasonable guidelines for researchers to observe:

- When a computer database with research related information is kept, the privacy and security procedures must be documented on the Application for Human Subjects Review form.
- Procedures should include physical security of the computer and memory devices, specifically designated (and limited) personnel access, and use of software security codes to permit data access and entry only to authorized research personnel.
- Information obtained from computer databases must only be used for research or to ensure subject safety.
- Hard copies containing confidential subject information must be stamped as confidential and access limited to person with designated “need to know” authority.
- All documentation gathered during the course of the research project must be destroyed at the end of the application retention period. The data may not be used for non-protocol purposes without each subjects’ written permission and may not be shared with non-involved researchers.
- At the conclusion of the research, project data stored on a computer shall be removed from the computer and any storage copies kept in a secure locked site as outlined in the original protocol.

Advertising for Subjects

Advertising for prospective volunteer subjects must receive prior approval by Institutional Research or the HSRC as part of the application process. Coercive statements must be avoided and any potential risks must be clearly identified. Compensation may be mentioned but no dollar amount should be indicated in any advertising. The level of compensation must be commensurate with the time and inconvenience involved and must not be in amounts which could be construed as economically coercive. The College’s Vice President of Finance should be consulted for an acceptable process to disburse human subject payments.

Students play an integral role as subjects in research concerning topics such as teaching methods; however, it is critical that students’ participation is voluntary. The classroom environment, by its very nature, creates unintentional coercion due to the relationship between the student and instructor. For this reason, instructors must avoid involving their own students as research subjects. Faculty who wish to involve their own students as subjects should be able to provide a good scientific reason, rather than convenience, for selecting those students as research subjects. The research project should be relevant to the topic of the class and participation should be part of the learning experience for the students. In instances where investigators can provide a good reason for involving their own students in their research, someone other than the primary investigator (instructor) should obtain informed consent and collect the data.

Financial Disclosures

Information regarding research funding is relevant to the extent that it may result in “undue inducement” to either the researcher or to the subjects (i.e., unjustifiable subject compensation which could have an adverse effect on



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the risk-benefit ratio). Consequently, the project application must include both the source and amount (either total or per-capita) of funding. The reviewing entity reserves the right to request a more detailed budget breakdown in order to assess risk-benefit in a particular study. The reviewing entity may request a clearer disclosure of what expenses are, or should be covered by the research funding, or an alteration of the subject payments if these are felt to be coercive.

Liability Statement

Liability for research related injury is a legal issue and is not covered by the policies herein. The contractual relationship between the sponsor, the researcher, and the institution will provide details of liability. The consent form should contain standard information as set out in the sample forms and should contain a statement such as “questions regarding liability are to be discussed with the researcher.”

Informed Consent

Informed consent is fundamental to research involving human subjects as they must participate willingly after having been informed about the research and how they will be involved. A consent form must be signed by each participant involved in the study. If research data is obtained from human subjects via online surveys, the researcher must include an “accept” or “decline” option in lieu of a signed consent form from each subject participating in the survey.

The consent form must be written in language easily understood by the subject. Technical terms should be avoided or if needed, explained thoroughly in simple language. The following elements should be address in an informed consent form:

1. Nature and purpose of the research
2. Nature of the subject’s involvement-what activities and for how long
3. Potential risks or discomforts for the subject
4. Potential benefits of the research for society and for the subject
5. Indication that the subject’s participation is voluntary
6. Indication that the subject may withdraw at any time without prejudice
7. Procedures for maintaining confidentiality/anonymity
8. Name and phone number of the person who the subject is to contact with questions or concerns about the research
9. Statement of liability, including indication that the subject does not waive any legal rights by signing the form
10. Signature by subject agreeing to participate in study and by researcher attesting to disclosure requirements and legality of the subject’s signature.

The consent form templates are on Knowledgebase, the Institutional Research webpage, and through the Institutional Research Office.

Research Reports and Publications

At the conclusion of the study, the researcher is required to provide Eastern Arizona College Institutional Research with copies of the documents such as annual or final reports to granting agencies, papers presented at professional meetings, and publications based on the research conducted through permission of Institutional Research. In addition, human subjects involved with the study should be provided with final results or publications should they request them.

