Whenever a Principal Investigator/Project Director (PI/PD) affiliated with Eastern Kentucky University engages in a project that involves human subjects, EKU must ensure compliance with federal policies safeguarding human subjects. This applies to all university projects involving human subjects whether funded from internal or external sources.

Eastern Kentucky University and the federal government require that the proposed project be reviewed and approved by the Institutional Review Board (IRB) and remain subject to continuing review by the IRB. In particular, funds administered by a department or agency may not be expended for projects involving human subjects until reviewed and approved by the IRB.

To be in compliance, EKU must establish the IRB to review proposed and ongoing research and provide the following:

1. A statement of principles governing EKU in the discharge of its responsibilities for protecting the rights and welfare of human subjects in projects conducted at or sponsored by the institution.
2. A list if IRB members identified by name, earned degrees, and representative capacity.
3. Written procedures which the IRB will follow:
   a. For conducting initial and continuing reviews of project activities.
   b. For reporting its findings and actions to the PI/PD and appropriate university officials.
   c. For ensuring prompt reporting to the IRB of proposed changes in project activity, and for ensuring that these changes not be initiated without IRB review and approval.
   d. For ensuring prompt reporting to the IRB, university officials, and the appropriate funding source of any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB or any suspension or termination of IRB approval.

Entities Affected by the Policy

- Students, faculty, and staff in departments, colleges, or units conducting activities involving humans as research subjects
- Subrecipients participating in activities involving human research subjects
- IRB members
- Sponsored Programs staff

Policy Statement

This policy has not yet been reviewed under Policy 1.1.1. For purposes of cataloging, it has been placed in an abbreviated form of the policy template. It remains an official university policy and will eventually be reviewed under Policy 1.1.1.
Membership of the Institutional Review Board (IRB)

Federal Requirements Regarding Membership. The composition of the IRB is detailed in 45 CFR Part 46 as follows:

1. The IRB shall have at least five members, with varying backgrounds, to promote an adequate review of the project activities.
2. The IRB shall be sufficiently qualified through the experience, expertise, and diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to issues such as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.
3. If the IRB regularly reviews projects that involve a vulnerable category of subjects, such as children, prisoners, pregnant women, handicapped, cognitively impaired persons, terminally ill patients, minorities, elderly persons, or economically or educationally disadvantaged persons, and even normal (i.e., healthy) volunteers such as students and employees or international subjects, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.
4. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
5. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family if a person who is affiliated with the institution.
6. A simple majority of the members if the IRB shall constitute a quorum with the stipulation that at least one member whose primary concerns are nonscientific areas must be present for the IRB to review proposed projects. For the project to be approved, it must receive the approval of the majority of those members present at the meeting.
7. No IRB may have a member participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
8. The IRB may, in its discretion, invite individuals with expertise in special areas to assist in the review of issues which require expertise beyond that available on the IRB. These individuals may not vote with the IRB.

University Requirements Regarding Membership. In addition to the federal requirements for IRB membership, there are several university requirements as follows:

1. In accordance with the university committee structure, the IRB reports to and advises the Associate Vice President for Research and Dean of the Graduate School on issues related to human subjects in research.
2. All members of the IRB are appointed by the President or his/her designee, as are two alternates.
3. The Chair shall be the Director of Sponsored Programs and shall be a non-voting member.
4. The Legal Counsel shall be the University Counsel and shall be a non-voting member.
5. Members’ terms are three years, staggered, so that the majority of the members are retained each year; members may serve no more than two terms in sequence.
6. Support services are provided by the Office of Sponsored Programs with all records being maintained in that office.
7. Minutes are copied to the Dean of the Graduate School, the appropriate PI/PD, and to the IRB.

Duties and Responsibilities of the IRB

1. The IRB must review proposed projects involving human subjects prior to initiation of the research. If such activity is undertaken without the intention of involving human subjects, but the PI/PD later proposes to involve human subjects, the revised project must be reviewed and approved by the IRB before it proceeds.
2. The IRB has the authority to approve, require modification of, or disapprove research or project activities.
3. The IRB shall require the PI/PD to provide documentation of informed consent.
4. The IRB shall notify the PI/PD and the appropriate institution official(s), in writing, of its approval or disapproval of a proposed project, or of modifications required to secure IRB approval. If the IRB disapproves a project, it shall include in its written notification a statement of the reasons for its decision and give the PI/PD an opportunity to respond. Even in disapproval, the IRB will always work with the PI/PD to revise the project to allow for approval.

5. The IRB shall conduct continuing review of continuing projects covered by this policy at intervals appropriate to the degree of risk, but not less than once a year. In addition, the IRB shall have authority to observe or have a third party observe the consent process and the project activity.

6. The IRB has authority to suspend or terminate approval of a project that is not being conducted in accordance with the requirements of the IRB, or that has been associated with unexpected serious harm to subjects, researchers, or a PI/PD. Any suspension or termination shall include a statement of the reasons for the action of the IRB and shall be reported promptly to the PI/PD, university officials, and the appropriate funding sources.

7. When appropriate, the IRB shall prepare and maintain adequate documentation of IRB activities, including the following:
   a. Copies of all proposals reviewed; scientific evaluations, if any, that accompany the proposals; approved sample consent documents; progress reports submitted by the PI/PD and reports of injuries to subjects.
   b. Minutes of IRB meetings shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on the actions, including the number of members voting for, against, and abstaining; the basis for requiring changes in or for disapproval of project activity; and a written summary of the discussion of controverted issues and their resolution.
   c. Records of continuing review activities.
   d. Copies if all correspondence between the IRB and the PI/PD.
   e. A list of IRB members identified by name, earned degrees, representative capacity, indications of experience, such as board certifications, licenses, etc., sufficient to describe each member’s anticipated contributions to IRB deliberations.
   f. Changes in IRB membership, as necessary.

**Type of Review**

The IRB will require that the PI/PD of any project involving human subject submit to the IRB an appropriate request for review. If the project is submitted to the funding agency prior to submission to the IRB, the IRB staff will indicate on the appropriate page that the proposal is pending and/or furnish to the PI/PD a statement if the IRB status of the proposed project.

Projects involving human subjects will be in one of three categories for IRB review: exemption from review, expedited review, or full review.

**Exempt from Review**

For a project to be exempted from review, the PI/PD must file a Review Application and Protocol as well as an Exemption Request with the IRB.

1. Exemption from review will be granted by the Chair of the IRB, or the Chair designee, to projects falling within the categories described in 45 CFR Part 46.110 and /or amendments to the list, if any. The Chair or the Chair designee may require additional information to determine exemption eligibility. **Exemption from review will not be granted for projects using vulnerable populations such as those described in this policy.**
2. When the above review procedure is used, the IRB members shall be informed of protocols which have been approved under the procedure. Upon the request of the IRB, additional information will be made available.
3. Records of all exemption requests will be kept on file in the Office of Sponsored Programs for a minimum of three years.

**Expedited Review**

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At the request of the PI/PD, the IRB will review, through an expedited procedure, projects involving no more than minimal risk to subjects. The IRB may also use the expedited review procedure to review minor changes in previously reviewed projects during the period for which the approval is authorized.

1. Expedited review will be conducted for projects having minimal risk and classification in one of the expedited review categories described in 45 CFR Part 46.110.

2. Expedited review is not allowed for projects where children are the subjects. Some funding agencies may have stipulations regarding the age of children and the PI/PD must be in compliance with those stipulations. Eastern Kentucky University will comply with the requirements set forth in 45 CFR part D, which provides additional protection for children involved in projects.

3. One copy of the Expedited Review Application and Protocol will be submitted to the IRB for review. The review may be carried out by the IRB Chair or by one or more experienced reviewers designated by the Chair from among the voting members of the IRB.

4. Approval will be given if the IRB member(s) and/or the Chair agree that the project meets the criteria for expedited review and for IRB approval.

5. The IRB member(s) conducting the expedited review may exercise all of the authorities of the IRB except that the reviewer(s) may not disapprove the project. The reviewer(s) shall refer any protocol which the reviewer(s) would have disapproved to the full committee for review. The reviewer(s) may also refer other protocols to the full committee whenever full committee review is warranted.

6. When the expedited review procedure is used, the IRB Chair or member(s) conducting the review shall inform IRB members if protocols which have been approved under the procedure.

Full IRB Review

When not eligible for exemption or expedited review, each proposal will follow an approved format known as a human subjects protocol. This protocol includes the following sections: purpose, background, study methodology, risks and precautions, procedures to maintain confidentiality, consent form, number and type of subjects and controls, any necessary special approvals, location of the study, source of funds, and the names of those responsible for supervision (if appropriate).

Risk

The PI/PD bears the responsibility of assessing possible risks to human subjects involved in the project and of taking appropriate steps to minimize those risks wherever possible. Before it may approve projects, the IRB must determine that the following criteria are satisfied:

1. **Risks to subjects are minimized.** Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the project 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. Risk is minimized by using procedures which:
   a. are consistent with sound research design;
   b. do not unnecessarily expose subjects to risk; and
   c. whenever appropriate, utilize procedures already being performed on the subjects for diagnostic or treatment purposes.

2. **Risks to subjects are reasonable** in relation to anticipated benefits, if any, to subjects, and to the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the project (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the project).

Selection of Subjects

Federal regulations require that the IRB give special consideration to protecting the rights and welfare of particularly vulnerable subjects, such as children (anyone under age 18), prisoners, pregnant women, handicapped, cognitively impaired persons, terminally ill patients, minorities, elderly persons, economically or educationally disadvantaged persons, and normal volunteers such as students and employees or international subjects. Investigators need to take additional special precautions when involving such special cases of subjects.

1. **Equitable selection of subjects.** In making this assessment the IRB will take into account the purposes of the project and the setting in which it will be conducted. Of particular importance is the
Informed Consent

The IRB is responsible for safeguarding the consent process in addition to the entire project relationship to ensure open and free communication between the PI/PD and the prospective subject. The IRB, therefore, expects the PI/PD to follow the process of informed consent, that is, to explain to human subjects involved in a project: 1) the nature and aim of the project; 2) the subject’s role in the project; and 3) the possible risks to the subject’s physical, psychological, or emotional well-being. This explanation is necessary as individuals expect the PI/PD to follow the process of informed consent. If, however, these activities are intended solely for the practice and experience of the student investigators, IRB approval will not be necessary. Faculty are cautioned to have student investigators follow good research practices in obtaining informed consent from subjects in the project and maintaining confidentiality. The University is potentially liable for any project conducted under its auspices.

2. Pregnant Women. Any project in which women of childbearing potential are possible subjects may inadvertently include pregnant women. For information about additional protections of fetuses or pregnant women, consult Subpart B - Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women, and Human in vitro Fertilization, of 46 CFR Part 45.

3. Prisoners. Because of their incarceration prisoners may be under constraints which could affect their ability to make truly voluntary and uncoerced decisions regarding participation in a project. For information concerning additional protections of prisoners, consult Subpart C - Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, of 46 CFR Part 45.

4. Children or Minors. The special vulnerability of children makes consideration of involving them as subjects in projects particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations are - addressed in Subpart D - Additional Protections for Children Involved as Subjects of Research, of 46 CFR Part 45.

5. Students, Employees and Normal Persons as Subjects in Projects. Federal regulations do not provide explicit protections for students, employees, and normal (i.e., healthy) volunteers as subjects in projects. There are some special considerations for involving these groups in a project. Volunteers for whom no therapeutic benefit can result from participation in a project should be exposed to risks that are minimized to the greatest extent possible. Normal volunteers, including students and employees, should generally be recruited through announcements or advertisements rather than through individual solicitations. Personal solicitations increase the likelihood that participation will be the result of undue influence. PIs/PDs should also consider that students may be under age, in which case they would fall into two special classes as normal (i.e., healthy) and underage subjects.

6. Students as Conductors of Projects. Students are often required to conduct projects as part of the course work for a class. When that project involves human subjects, the project may require IRB review. The concern here is not for the students in the class but for the subjects of the project, who may or may not themselves be students. If the faculty member teaching the course and supervising those students conducting the project intends to, or may possibly make use of the student findings in his/her own work, then the student project should be submitted for IRB review and approval. If, however, these activities are intended solely for the practice and experience of the student investigators, IRB approval will not be necessary. Faculty are cautioned to have student investigators follow good research practices in obtaining informed consent from subjects in the project and maintaining confidentiality. The University is potentially liable for any project conducted under its auspices.

7. International Subjects in Projects. Human subjects projects conducted in foreign countries by American PIs/PDs require compliance with federal regulations for protection of human subjects in all material respects, just as they would if the project were conducted wholly within the United States. Further information about the above classes of subjects and other specialized populations may be found in Protecting Human Research Subjects: Institutional Review Board Guidebook, by the Office of Protection from Research Risks (OPRR).
1. **General Requirements for Informed Consent.** Prospective human subjects shall be given the following information in language understandable to the subject:
   a. an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
   b. a description of any reasonably foreseeable risks or discomforts to the subject.
   c. a description of any benefits to the subject, if any, which may reasonably be expected from the research.
   d. a disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject.
   e. a statement describing the extent to which confidentiality of records identifying the subject will be maintained.
   f. a statement describing the extent of confidentiality of subject records.
   g. an explanation of possible compensation and medical treatment in the event of injury from research involving more than minimal risk.
   h. an explanation of contact persons regarding the research, subjects’ rights, and potential research-related injury.
   i. a statement that participation is voluntary and the subject may discontinue participation at any time, and that refusal to participate or withdraw from the project will involve no penalty or loss of benefits to which the subject is otherwise entitled.

2. **The Consent Form.** The PI/PD may use the consent form provided by the IRB or may devise a consent form that contains the same basic elements. If the PI/PD devises a different consent form, it must be written in language easily understandable to the subjects. The possibility of illiteracy should be considered as should the need for communication in a foreign language. The subject must be given adequate opportunity to read the form before signing it.

The written consent form shall state that the subject has agreed to participate in the project. The written consent form may either provide the subject with the basic information required by the federal government as outlined above, or it may simply state that this information has been presented orally. If this information is all presented orally, the investigator must have a witness to the oral presentation.

When children or minors are involved in projects, regulations require the assent of the child or minor along with the permission of the parent or guardian. PIs/PDs should be aware that many college students are under age, and therefore need to obtain, in addition to the subject’s consent, the permission of a parent or guardian to the subject’s participation in the project. The subject’s parent or guardian must be given adequate opportunity to read the form before signing it.

3. **Waiving of Informed Consent.** The IRB may approve a consent procedure which does not include or which alters some or all of the elements of informed consent set forth in this section provided the IRE finds and documents that:
   a. the research involves no more than minimal risk to the subjects;
   b. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
   c. the research could not practically be carried out without the waiver or alteration.
   d. when appropriate, the subjects will be provided with additional pertinent information after participation.

The IRB may also waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
   a. that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. In this case, each subject will be asked whether he or she wants documentation linking him or her with the research, and the subject’s wishes will prevail.
   b. that the research presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required outside of the research content.

For other exceptional circumstances under which the IRB may waive or alter the requirement to obtain an informed consent, see Sections 46.116 and 46.117 of 45 CFR Part 46.

**Privacy**

The IRB must ensure that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. This is required regardless of the population from which the subjects for the project are selected.
Definitions

<table>
<thead>
<tr>
<th>Term</th>
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<tr>
<td>Assent</td>
<td>A child's affirmative agreement to participate in research. Mere failure to object to should not, absent affirmative agreement, be construed as assent.</td>
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<td>Beneficence</td>
<td>Obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risk of harm.</td>
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<td>Children</td>
<td>Persons who have not attained the legal age for consent, which in Kentucky, is anyone under the age of 18.</td>
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<td>Human Subject</td>
<td>A living individual about whom an investigator (whether professional or student) conducting research obtains data (a) through intervention or interaction with the individual or (b) identifiable private information.</td>
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<tr>
<td>Institution</td>
<td>Eastern Kentucky University</td>
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<tr>
<td>Institutional Review Board (IRB)</td>
<td>The EKU body charged with ensuring the University's compliance with federal regulations governing the protection of human research participants.</td>
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<tr>
<td>Interaction</td>
<td>Communication or interpersonal contact between investigator and subject</td>
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<tr>
<td>Intervention</td>
<td>Both physical procedures by which data are gathered and manipulations of the subject or subject's environment that are performed for research purposes</td>
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<td>Justice</td>
<td>Fairness in distribution of research benefits</td>
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<td>Private information</td>
<td>Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).</td>
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<tr>
<td>Research</td>
<td>An activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalized knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective (Belmont Report). As defined by 45 CFR Part 46, research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.</td>
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<tr>
<td>Respect of Persons</td>
<td>Recognition of the personal dignity and autonomy of individuals with special protection of those persons with diminished autonomy.</td>
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<td>University</td>
<td>Eastern Kentucky University</td>
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Violations of the Policy

Failure to comply with this policy could result in the termination or suspension of the applicable project.

Interpreting Authority

Associate Vice President for Research

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### Statistical or Regulatory References

Code of Federal Regulations for Protecting Human Research Subjects

### Policy Adoption Review and Approval

#### Policy Revisions

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<td>Council on Academic Affairs</td>
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<tr>
<td>May 3, 1999</td>
<td>Faculty Senate</td>
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<tr>
<td>July 29, 1999</td>
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#### Policy Issued

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