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Section 12, Protecting Human Subjects in Research

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Protecting Human Subjects in Research

Policy Statement

In compliance with Title 45 Code of Federal Regulations Part 46 (45 CFR 46), *Protection of Human Subjects*, the University is responsible for ensuring that research investigators protect the rights, privacy, and welfare of individuals recruited for participation in research. The Institutional Review Board (IRB) is responsible for overseeing the use of human subjects in research projects conducted at the University or conducted by University faculty, staff, or students at locations other than those owned by the University. The jurisdiction of the IRB includes the authority to review, approve, require modifications to, or deny approval of research protocol applications submitted by faculty, staff, and student investigators. The process of review serves to ensure the safe and ethical conduct of research that ultimately will protect the rights and welfare of human subjects in an atmosphere of mutual trust and scientific integrity in the pursuit of knowledge. All research projects shall be submitted for IRB review and approval prior to the initiation of research activities. The IRB authority and jurisdiction is outlined further within this policy.

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 Background

The National Research Act of 1974 established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This Commission published the Belmont Report articulating the ethical principles that guide the conduct of research with human subjects and continue to serve as the foundation of Title 45 Code of Federal Regulations Part 46 (45 CFR 46). In the design, conduct, approval and review of research, ECU officials, IRB members, and investigators adhere to the basic principles set forth in the Belmont Report: respect for persons, beneficence, and justice.

The purpose of this policy is to outline the University's accountability with regard to the protection of human research subjects. The policy explains the responsibilities of individuals participating in activities involving the use of human research subjects and of the IRB.

Institutional Review Board (IRB) Authority and Jurisdiction

IRB Authority

The IRB has the authority to:

- Review and approve, require modifications in (to secure approval), or deny approval for all research activities covered by this policy
- Conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year
- Observe or have a third-party (internal to EKU or from an external organization) observe the consent process or the research and review the research documentation
- Suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with serious harm to subjects

IRB Jurisdiction

45 CFR, Part 46, *Protection of Human Subjects* defines research as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." Projects that meet the criteria outlined in this definition that are conducted at the University or conducted by University faculty, staff, or students at locations other than those owned by the University are subject to review and approval by the IRB. This policy is applicable regardless of whether the project involves funding from an external agency.

Systematic investigations conducted by graduate or undergraduate students that involve the use of humans as subjects and that are intended to contribute to generalizable knowledge must be reviewed and approved by the IRB. This includes, but is not limited to, independent undergraduate research projects and honors theses, graduate theses, and dissertations.

Class projects that are designed to teach research methods to students, however, are not typically classified as research and therefore are not ordinarily subject to IRB review. These projects are overseen by an advising faculty member, who is responsible for ensuring that appropriate precautions are taken with regard to the protection of participants. While most class assignments are designed to teach research methods and are not the type of activities typically overseen by the IRB, there are instances when the nature of these projects is such that participants could be put at risk of harm. Class projects involving participants outside the classroom are subject to IRB review if they meet either of the following criteria:

1. Are undertaken with the intention of producing results that will be submitted for peer-reviewed publication or presentation or otherwise made available to a broad general audience
2. Involve any type of activity that places the participants at more than minimal risk, considering both the probability and the magnitude of harm

Policy Procedures

Selection and Operation of the Institutional Review Board

The IRB shall be composed of at least five members with varying backgrounds to promote an adequate review of research protocols. The IRB shall include at least one member whose primary concerns are in a scientific area and at least one member whose primary concerns are in a nonscientific area. The IRB shall include at least one member who is not otherwise affiliated with the University and who is not part of the immediate family of a person who is affiliated with the University. The IRB shall not be composed entirely of members of one profession, and efforts will be made to assure a diverse membership in regard to gender, ethnicity, and culture.

1. Membership shall be appointed by the University's president or his/her designee. Two or more alternates may also be appointed to function in the absence of a voting member if necessary.
2. The University's IRB voting membership shall include faculty/staff members representing areas in which human subject research typically occurs and at least one person with no affiliations with the University.
3. Representatives from the offices of Sponsored Programs, Institutional Research, and University Counsel shall also serve on the IRB as non-voting ex-officio members.

4. The IRB may, at 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.
5. Each voting IRB member shall be appointed to a term of not more than three years, and no member may serve more than two consecutive three-year terms.
6. No IRB member shall 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.

IRB Review Considerations

In reviewing research protocols, the IRB shall consider the following:

- **Risks and Benefits:** The IRB assesses whether the risks to participants are reasonable in relation to the anticipated benefits to the participants or to society. In particular, the IRB reviews proposed studies to ensure that the risks are minimized to the greatest extent possible. To an extent, the IRB considers the scientific merit of the study design because it would be unethical to place human subjects at risk for a study with flawed methodological procedures likely to yield little or no reliable information.
- **Equitable Selection of Research Participants:** The selection of participants should be equitable and free of coercion. The IRB considers the research setting and study purposes, including whether the proposed study intends to involve vulnerable and special classes of subject populations such as children, students, prisoners, subjects with cognitive disorders, or economically disadvantaged individuals.
- **Identification of Participants and Confidentiality:** The IRB considers the methods for the selection of and contact with participants, including how participants' privacy and confidentiality will be insured. The IRB also considers the importance of the research, the sensitivity of information sought from participants, and the special procedures devised by the investigator for protecting private or personal information.
- **Informed Consent:** The IRB reviews the process described by the investigator for obtaining informed consent, including where, when, and how consent will be obtained.

Exempt Review Procedures

Projects that are exempt from human subject regulations must be classified as such through review by the IRB. To qualify for exemption, the only involvement of human subjects must be in or more of the following categories as defined by 45 CFR, Part 46, *Protection of Human Subjects*:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category two, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs

6. Taste and food quality evaluation and consumer acceptance studies, if: (i) wholesome foods without additives are consumed; or (ii) a good is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the United States Department of Agriculture

If any activity falls outside of these categories, the research must be reviewed through expedited or full review procedures. Research protocols submitted for IRB review for exempt status shall be forwarded to one of the voting faculty/staff committee members on a rotating basis for review and approval.

Expedited Review Procedures

Certain types of research that involves no more than minimal risk may be reviewed through the expedited review process. To be eligible for expedited review, a project must present no more than minimal risk and involve only procedures in one or more of the research categories outlined below. Unless otherwise noted, these categories are applicable regardless of the age of the subjects. The expedited review procedure does not apply where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal. The research categories designated by 45 CFR, Part 46, *Protection of Human Subjects* as eligible for expedited review are as follows:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a. Research on drugs for which an investigational new drug application is not required. Note that research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.
 - b. Research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b. From other adults and children considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) Hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples include: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity,

- electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). Note that some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.
 6. Collection of data from voice, video, digital, or image recordings made for research purposes.
 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Note that some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.
 8. Continuing review of research previously approved by the convened IRB as follows:
 - a. Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - b. Where no subjects have been enrolled and no additional risks have been identified; or
 - c. Where the remaining research activities are limited to data analysis.
 9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

If any activity falls outside of these categories, the research must be reviewed through full review procedures. Research protocols submitted for IRB review for expedited review shall be forwarded to one of the voting faculty/staff committee members on a rotating basis for review and approval.

Full Review Procedures

Research protocols for projects involving greater than minimal risk shall be submitted for full IRB review during a convened meeting of all IRB members. Meetings are scheduled on a monthly basis during the academic year and are scheduled between semesters as needed for the review of research protocols. A simple majority of the members of the IRB shall constitute a quorum with the stipulation that at least one member whose primary concerns are in a nonscientific area shall be present for the review. For the project to be approved, it must receive the approval of a majority of those members who are present at the meeting.

At its discretion, the IRB may also request full review for other projects, particularly those that involve protected populations of subjects, regardless of the level of risk involved. Protected populations include children, prisoners, mentally impaired individuals, and pregnant women and fetuses.

IRB Investigator and Key Personnel Training

Investigators (including students), key personnel, and faculty advisors (for student projects) shall be required to complete training on the use of human research subjects by completing an educational program that is acceptable to the IRB and shall furnish a copy of training documentation prior to submitting research protocols for IRB approval. Training documentation is valid for a period of three years, after which time, investigators shall furnish updated training documentation. Current training documentation is required for all investigators, key personnel, and faculty advisors prior to the approval of research protocols submitted for IRB review.

Ensuring Informed Consent

In clear and non-technical language which is appropriate to the subject, subjects must be informed of:

1. The fact that the study is research;
2. The purposes of the research;
3. The expected duration of the subject's participation;
4. The procedures to be followed;
5. Any reasonably foreseeable risks or discomforts;

6. Any benefits to the subject or to others which may reasonably be expected from the research;
7. Appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject;
8. The extent, if any, to which confidentiality of data and privacy of subjects will be maintained;
9. For research involving more than minimal risk, whether any compensation and whether any medical treatments are available if injury occurs;
10. Whom to contact for answers to pertinent questions about the research, subjects' rights, and research-related injury to the subject; and
11. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study.

Informed consent shall be documented by having the subject (or legally authorized representative) sign the written consent form and receive a copy of the form. The investigator or research team member must also sign the consent form. The IRB may waive the requirement to obtain a signed consent form if it finds either:

1. That the only record linking the subject to the research would be the consent form and the most serious risk would be breach of confidentiality; or
2. That the research involves no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context.

For research studies of minimal risk involving the use of questionnaires, the required elements of informed consent may be included in an introductory letter or information attached to the instrument which includes a statement that completion and return of the questionnaire (hard copy or electronic) will constitute consent to participate in the study.

Research Involving Children

While there are often compelling reasons for including children as research subjects, research involving children should be avoided unless the use of adults in the research would not provide access to the data needed for a particular research protocol. The exemption categories are applicable regardless of a subject's age with the exception of parts of exemption category 2. Research involving the use of educational tests with minors is exempt. However, the exemption for research using survey or interview procedures does not apply to research involving children, and the exemption for observations of public behavior does not apply to research involving children if the investigator participates in the activities being observed.

Additional precautions are required for research involving children that does not qualify for exemption. For projects to be approved through expedited or full review procedures, adequate provisions must be made for soliciting the permission of the children's parents or guardians as well as the assent of the children, when in the judgment of the IRB, the children are capable of providing assent. In determining whether children involved in the research are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children involved in a protocol or for each child, as the IRB deems appropriate.

Children who are wards of the state may participate in research activities only if the activities are related to their status as wards or are conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

The IRB may waive the assent and parental permission requirements in accordance with the provisions for waiving informed consent. In addition, the IRB may waive parental permission requirements if it determines that a protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (i.e., neglected or abused children) provided that an appropriate mechanism for protecting the children is substituted.

To approve research that represents greater than minimal risk to children, the IRB must be assured that the risk is justified by the anticipated benefit to the children and that the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by any available alternative approaches.

Research Involving Prisoners

Additional precautions are required for research involving prisoners, who because of their incarcerated state, may be under constraints that would prohibit their ability to make a truly voluntary and uncoerced decision of whether to participate in a research project. Research may involve prisoners only if the following conditions exist:

- The research must represent one of the following categories of permissible research:
 - Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that study involves no more than minimal risk and no more than inconvenience to the subjects
 - Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects
 - Research on conditions particularly affecting prisoners as a class
 - Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject
- Any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities, and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired
- The risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers
- Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners
- The information is presented in language that is understandable to the subject population
- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole
- Where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact

Research projects involving prisoners require full IRB review. A majority of the IRB members shall have no associations with the prison(s) involved. In addition, a special representative shall be appointed to participate in the protocol review who is a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity.

Continuing Review and Reporting Requirements

Projects approved as exempt are exempt from further review and come with no additional reporting requirements for the investigator unless the investigator wishes to modify the research design. Any changes from those outlined in the original application for exempt status must be reviewed and approved by the IRB prior to implementation, regardless of whether the changes result in a change in the project's exempt status.

Projects approved through expedited or full review procedures require annual continuing reviews. Not less than annually, investigators shall submit a completed continuing review form for each year the project is active. If the IRB determines that a project necessitates continuing review at more frequent intervals, the investigator shall be informed of the reporting requirements at the time when approval is granted.

Investigators are required to file a final report with the IRB within thirty days of the project's completion. If investigators wish to continue the project beyond the initial approval period, they shall request approval to do so prior to the project's expiration date.

Project Suspension and Termination

The IRB has the authority to temporarily suspend or permanently terminate approval of a research protocol that has been determined to not be conducted in accordance with the research protocol approved by the IRB or that has been found to represent unexpected serious harm to research participants. The IRB may also suspend or terminate research activities for which reporting requirements have not been followed.

In the event of project suspension or termination, the investigator will be notified in writing by the IRB immediately upon such action being taken by the IRB. In the case of a suspended project, the investigator will be provided with a list of conditions that must be met in order to continue with the research and a timeframe within which to comply. Research activities shall not resume until the investigator has been notified by the IRB that the suspension has been removed.

Reporting Problems with Approved Research

At the time of IRB approval, investigators are informed of their responsibility to immediately notify the IRB of any unexpected problems, injuries, or increased risks to human subjects participating in the research within 10 days of the occurrence. If no such events have been disclosed to the IRB, the investigator shall certify such on at least an annual basis through the continuing review and final reporting process.

If an individual other than the investigator believes that any research misconduct has taken place in the project, he or she shall immediately notify the institutional official. The institutional official shall form a review committee consisting of the IRB Chair and at least one other IRB member to conduct an investigation of the allegations, beginning with an interview with the research team. The results of the investigation shall be reported to the full IRB, who will be responsible for prescribing a corrective action plan to address the noncompliance or terminate the project altogether. The IRB has the authority to suspend the project at any point in the investigation following the initial interview with the research team.

Definitions

Adverse Event	An unexpected or serious negative event occurring in the conduct of a research project. All adverse events must be reported in writing to the IRB within 10 days of the occurrence.
Assent	A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
Beneficence	Requires that researchers maximize the potential benefits to participants, or to society, while minimizing the potential risks of harm. The extent of protection depends on the risks and benefits of the proposed research. All participants should be treated in an ethical manner. Benefits to participants, or in the form of generalized knowledge gained from the research, should always outweigh the risks. If there are any risks resulting from participation in the research, then there must be benefits, either to the participants or to society.
Children	Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. In Kentucky, the legal age for consent is eighteen years.
Deception	Deception occurs when an investigator intentionally tells participants something that is not true. Studies involving deception are not eligible for exemption, and deception is not permitted in studies involving greater than minimal risk.

Federalwide Assurance (FWA)	A written agreement that establishes standards for human subjects' research as approved by the federal Office for Human Research Protections and is executed by the institutional official.
Human Subject	A living individual about whom an investigator conducting research obtains (i) data through intervention or interaction with the individual or (ii) identifiable private information.
Informed Consent	Requires that participants are provided with information about the research project to assist in their informed decision of whether to participate, are given explicit assurances of the voluntary nature of their involvement in terms that are easy to understand, and are not under duress or pressured to serve as participants.
Institutional Official	The individual with the authority to provide compliance assurances to federal agencies and for issuing other official documentation on behalf of the University. EKU's institutional official is the Associate Vice President for Research.
Institutional Review Board (IRB)	The EKU body charged with ensuring the University's compliance with federal regulations governing the protection of human research participants.
Interaction	Communication or interpersonal contact between investigator and subject
Intervention	Both physical procedures by which data are gathered and manipulations of the subject's environment that are performed for research purposes
Justice	Requires that subjects be selected fairly and that both the risks and benefits of research are distributed evenly. Investigators should take precautions not to select participants simply because of convenient availability, manipulability, their compromised positions, or because of social, racial, sexual, economic, or cultural biases institutionalized in society.
Minimal Risk	The probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons
Prisoner	Any individual involuntarily confined or detained in a penal institution. Prisoners are considered a protected population and may only be included in research activities when there is a compelling reason for their inclusion.
Private information	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.
Quorum	A simple majority of the voting members of the IRB
Research	A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge
Respect of Persons	Recognition of the personal dignity and autonomy of individuals with special protection of those persons with diminished autonomy. In addition, respect means honoring the privacy of individuals and maintaining confidentiality
University	Eastern Kentucky University

Responsibilities

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| Department Chairs | <ul style="list-style-type: none"> Review the technical merit of research protocols and recommend them for IRB review |
| Division of Sponsored Programs | <ul style="list-style-type: none"> Provide administrative support to the IRB, including the maintenance of applicable records, processing of research protocols for review, recording of minutes from IRB meetings, and other activities necessary for the efficient |

operation of the IRB

- Provide guidance to investigators on the interpretation of federal regulations governing the use of human research subjects
- Provide reports to all IRB members on projects that have been approved through the expedited review process or approved for exemption
- Manage the IRB training system and records
- Ensure that activities proposed for external support have been reviewed and approved by the IRB prior to the release of any awarded funds
- Facilitate the review and investigation of human subjects-related complaints from all sources
- Notify investigators of required reports and follow up on delinquent reports
- Update committee membership rosters with the Office of Human Research Participants when IRB membership changes
- File and update the University's Federal-wide Assurance to the federal Office of Human Research Protections as required

Faculty Advisors

- Complete and maintain current (every three years) certification in human subjects research for investigators by completing an educational program acceptable to the IRB (All members of student thesis committees for projects involving human research subjects are encouraged to complete training as well).
- Advise students throughout process of protocol development, submission, and review as well as in the implementation of the research project
- Guide students in the development of the research protocol to ensure that the content, quality, and timing of the submission meet the requirements of the IRB
- As the responsible investigator, ensure that student researchers are aware of their responsibilities as investigators and ensure that the IRB is immediately notified in the event of research-related unanticipated events or findings during the study that would affect the risks or benefits of participation
- Ensure the timely submission of required continuing review and final reports for student projects
- Maintain records related to student projects for a period of not less than three years from the date the final report is filed with the IRB

Institutional Official

- Oversee the University's compliance with federal regulations governing the protection of human research participants
- Approve the University's Federal-wide Assurance to the federal Office of Human Research Protections
- Serve as the primary contact for allegations of research misconduct and arrange for IRB investigations of such allegations

Investigators

- Complete and maintain current (every three years) certification in human subjects research for investigators by completing an educational program acceptable to the IRB
- Prepare the research protocol using forms provided by the IRB and reflecting compliance with this policy
- Be available to answer questions or make adjustments if needed during the IRB review process
- Implement and conduct the research activities as outlined in the IRB-approved research protocol
- Appropriately supervise students and other personnel involved in the project
- Immediately inform the IRB of any adverse reactions, injuries, or increased risks for human subject participants
- Request IRB approval for any changes needed in the research protocol and await approval prior to implementing changes
- Submit continuing review documentation on an annual basis or more frequently if requested by the IRB unless protocol has been approved for

IRB Chair

- exemption
- File the final report with the IRB within 30 days of the completion of the project or immediately upon discontinuing the project unless protocol has been approved for exemption
- Maintain records relating to the project for a period of three years from the date the final report is filed with the IRB and make available such records for inspection at the request at the IRB
- Immediately notify the IRB if leaving ECU, regardless of whether the investigator plans to continue the research at another institution
- Review research protocols in a timely manner
- Provide suggestions to investigators regarding submitted research protocols when needed
- Provide guidance to other IRB members during reviews of expedited protocols or applications for exemption
- Provide guidance to faculty, staff, and student investigators in the development of research protocols as requested
- Participate in the review of all research protocols submitted for full review
- Lead meetings of the IRB as scheduled or called
- Review documentation for annual reviews, requests for extensions, and requests for modifications for protocols approved through full review, projects reviewed by the Chair through the expedited review process, and projects reviewed through the expedited review process by members who are not currently on the IRB

IRB Members

- Participate in the investigation of allegations of research misconduct as requested by the Institutional Official
- Review research protocols in a timely manner
- Provide suggestions to investigators regarding submitted research protocols when needed
- Participate in the review of all research protocols submitted for full review
- Attend IRB meetings as scheduled or called
- Review documentation for annual reviews, requests for extensions, and requests for modifications for previously approved protocols reviewed by the IRB member through the expedited review process
- Participate in the investigation of allegations of research misconduct as requested by the Institutional Official

Violations of the Policy

Failure to comply with this policy could result in the termination or suspension of the applicable project and the ineligibility to publish research results of activities for which prior IRB approval was not granted, including publication in professional journals. Student theses and dissertations subject to this policy will not be published in the institutional archive or other online repositories without IRB approval. Requests for approval of new protocols will not be honored for investigators who have not filed required reports with the IRB in a timely manner.

Interpreting Authority

Associate Vice President for Research

Statutory or Regulatory References

Code of Federal Regulations for Protecting Human Research Subjects

Relevant Links

- [EKU Institutional Review Board website](#)
- [Code of Federal Regulations for Protecting Human Research Subjects](#)
- [Human Subjects Regulations Decision Charts](#)
- [Health and Human Services Policy Guidance](#)

Policy Adoption Review and Approval

Policy Revisions

<u>Date</u>	<u>Entity</u>	<u>Action</u>
January 26, 2011	Board of Regents	Adopted
December 13, 2010	President Doug Whitlock	Approved
November 3, 2010	Provost Council	Approved
September 20, 2010	Faculty Senate	Approved

<u>Date</u>	<u>Entity</u>	<u>Action</u>
July 29, 1999	Board of Regents	Adopted
May 3, 1999	Faculty Senate	Approved
April 22, 1999	Council on Academic Affairs	Approved

Policy Issued

<u>Date</u>	<u>Entity</u>	<u>Action</u>
March 21, 1973	Board of Regents	Adopted