Kutztown University Policy ACA-040

Human Subjects Research

A. Purpose

This policy is established for the purpose of protecting the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of Kutztown University; and in order to comply with Title 45 Code of Federal Regulations, Part 46, Protection of Human Subjects.

B. Scope

This policy applies to all research projects, conducted by students, staff and faculty, which involve human subjects.

C. Key words and phrases:

Research - a systematic investigation designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of these standards, whether or not they are supported or funded under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Human subject - a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual (including interviews, surveys, and participation in experiments); or

2. Identifiable private information.

Private information - includes both:

a. Information about behavior that occurs in circumstances where the individual can reasonably expect that no observation or recording is taking place; and

b. Information which the individual has provided for a specific purpose and which he or she can reasonably expect will not be made public (such as a medical record).

Identifiable - the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Institutional Review Board (IRB) - generic term used to designate the local institutional review committee which is required under the regulations to review research involving human subjects. At local institutions, these committees are given various names, such as committee on human subjects, or the human investigations committee.

Certification - term used to denote the documentation that must be sent to potential funding agencies to certify that the proposed research project has been reviewed and approved by an Institutional Review Board (i.e., a human subjects review committee).

Code of Federal Regulations (CFR) - a compendium of rules issued by Federal agencies.

Competence - a legal term, used to denote capacity to act on one's own behalf, the ability to understand information presented to appreciate the consequences of acting (or not acting) on that information, and to make a choice.

Confidentiality - pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

Informed Consent - a person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic or preventive procedure.

Minimal Risk - risks of harm anticipated in proposed research that are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or in the performance of routine medical or psychological examinations.

Principal Investigator (investigator) - the scientist or scholar with primary responsibility for the design and conduct of a research project.

Privacy - control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally or intellectually) with others.

D. Policy & Procedure(s)

Kutztown University’s policy is that no research done under its jurisdiction expose persons who participate as subjects or respondents to unreasonable risks to their health, general well-being, or privacy.

The IRB reviews research, conducted by students, staff and faculty, which involve human subjects. This document defines the makeup of the IRB and its functions. The approval of the IRB is a requirement for research projects involving human subjects.

INTRODUCTION

A. Composition of IRB

1. The IRB shall have a minimum of five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

2. The IRB will not consist entirely of men or of women.

3. 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.

4. IRB shall include at least one member selected who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

5. No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

6. An IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

7. Faculty IRB committee members shall be appointed by the Committee on Committees. The Provost will appoint one administrator and a person not affiliated with the university.

B. Functions and Operations

1. The Provost will appoint a chair of the IRB.

2. The IRB will notify the university community of a meeting schedule. Except when an expedited review procedure is used, the IRB will review proposed research at regularly convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

C. Review of Research

1. The IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this human subjects policy.

2. The IRB shall require that information given to subjects as part of informed consent is in accordance with 45 CFR 46.

3. The IRB shall require documentation of informed consent or may waive documentation in accordance with 45 CFR 46.

4. The IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or of modifications required to secure IRB approval of the research activity. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

5. The IRB shall conduct continuing review of research covered by this policy (except protocols determined by the IRB to qualify for exempt status) at intervals appropriate to the degree of risk, but not less than once per year, and shall have authority to observe or have a third party observe the consent process and the research.

D. Criteria for Approval of Research

1. In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

a. Risks to subjects are minimized: (1) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (2) whenever appropriate by using procedures already being performed on the subjects for diagnostic or treatment purposes.

b. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and in relation to the importance of the knowledge that may reasonably be expected to result.

c. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

d. Informed consent will be sought from each prospective subject or the subject's legally authorized representative. The requirement for a signed consent may be waived by the IRB. When waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

e. Informed consent will be appropriately documented.

f. When appropriate, the research plan makes adequate provision for monitoring data collected to ensure the safety of subjects.

g. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

h. When some or all of the subjects are likely to be vulnerable for coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

E. Suspension or Termination of Research

1. Unanticipated problems involving risk to subjects or others must be reported immediately to the IRB and may lead to suspension or termination of research.

2. Serious or continuing noncompliance with federal regulations or the requirements or determinations of the IRB may lead to suspension or termination of research.

3. An IRB shall have authority to suspend or terminate approval of research. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head supporting the research, and any other necessary parties.

F. Records

1. The IRB shall prepare and maintain adequate documentation of activities, including the following:

   a. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

b. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings, actions taken by the IRB, the vote on these actions including the number of members voting for, against, and abstaining, the basis for requiring changes in or disapproving research, and a written summary of the discussion of controverted issues and their resolution.

c. Records of continuing review activities.

d. Copies of all correspondence between the IRB and the investigators.

e. A list of IRB members in detail.

f. Written procedures for the IRB in detail.

g. Statements of significant new findings provided to subjects.

2. The records required by this policy shall be retained for at least (3) three years.

3. Records relating to the approved research (e.g., consent forms), must be retained by the investigator for at least (3) three years after completion of the research. An investigator who leaves the university prior to the end of the 3-year retention period must notify the IRB, specifying the new location of the records. If records are maintained by a student or research assistant, the records must be turned over to the faculty member after the research has been conducted.

G. Types of Review

The role of the University's IRB is to ensure compliance with University policy as well as with applicable federal regulations for funded research as detailed in the CFR, (45 CFR Part 46), and any other federal regulations currently in force or which may be introduced in the future.

There are three general categories of review.

1. Exempted Review. There are several broad categories of social science, educational, and economic research which may be exempt. The Chair of the IRB determines whether a particular research project is exempt. As necessary, the Chair will consult with members of the IRB when making a decision on exemption requests. If exempt, the investigator will be so notified by the Chair.

   IRB exemption will have no expiration date. However, any revisions/changes to the research protocol affecting human subjects may affect the original determination of exemption and therefore must be submitted for review and subsequent determination.

   The following categories are considered eligible for Exempted Review:

a. 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.

b. 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.

c. 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 paragraph (b) of this section, 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.

d. 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.

e. 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.

f. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food 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 U.S. Department of Agriculture.

2. Expedited Review. Research activities involving no more than “minimal risk” may be eligible for Expedited Review.

Protocols will be reviewed by the Chair and/or one or more experienced committee members. The reviewer(s) may either approve the protocol or refer it for full committee review. In the event the reviewer(s) does not approve the protocol under expedited review, the Chair will contact the investigator about the next step in the review process. Expedited review may also be used to approve minor changes in the protocol of an approved project.

The categories of research eligible for Expedited Review are:

a. Clinical studies of drugs and medical devices only when condition (i) or (ii) is met.

   (i) Research on drugs for which an investigational new drug application is not required. (Note: 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.)

   (ii) Research on medical devices for which an investigational device exemption application is not required; or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

   (i) 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

   (ii) 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.

c. Prospective collection of biological specimens for research purposes by noninvasive means.

   Examples: (i) hair and nail clippings in a nondisfiguring manner; (ii) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (iii) permanent teeth if routine patient care indicates a need for extraction; (iv) excreta and external secretions (including sweat); (v) 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; (vi) placenta removed at delivery; (vii) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (vii) 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; (ix) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (x) sputum collected after saline mist nebulization.

d. 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: (i) 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; (ii) weighing or testing sensory acuity; (iii) magnetic resonance imaging; (iv) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (v) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

e. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

f. Collection of data from voice, video, digital, or image recordings made for research purposes.

g. 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.

3. Full Committee Review. Any research not covered by the conditions of Exempted Review or Expedited Review, including all research which involves more than "minimal risk," or which could not be approved using other review categories, will be referred to the IRB for full review.

H. Reporting and Continuing Review

1. Investigators must ensure prompt reporting to the IRB of proposed changes in a research activity and ensure that such changes in approved research, during the period for which IRB approval has already been given, will not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to the subjects.

This reporting is required for all approved research, whether the determination was exempt, expedited or full. Note that changes to the research may affect the original determination and, therefore, must be submitted for review and subsequent determination.

2. Investigators must ensure prompt reporting to the IRB of any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with federal regulations or determinations of the IRB.

3. Investigators must report progress of approved research to the IRB as often as, and in the manner, prescribed by the IRB.

4. IRB conducts continuing review of ongoing research (except protocols determined by the IRB to qualify for exempt status) at intervals appropriate to the degree of risk, but not less than once per year. For approved research, the IRB determines which activities require continuing review more frequently than every 12 months.

I. Informed Consent and Assent

In most research activities, the investigator must obtain informed consent from each subject or the subject's legally authorized representative (e.g., parent, guardian or legal representative). An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. In situations where full disclosure of the purpose of the research is not possible because it could bias the outcome, the investigator has the responsibility to debrief subjects concerning the purpose of the research.

Basic elements of informed consent that must be communicated in clear, non-technical and age appropriate language that subjects can understand:

1. A statement that the study involves research, 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.

2. A description of any reasonably foreseeable risks or discomforts to the subject.

3. A description of any benefits to the subject or to others which may reasonably be expected from the research.

4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.

8. 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 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.

There are two procedures, which may be used to obtain informed consent, written and orally.

1. A written consent document that embodies the elements of informed consent set forth above. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.

2. A short form written consent document, stating that the elements of informed consent, set forth above, have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation.

Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

Informed Consent Waivers:

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent. An IRB may also approve a consent procedure that waives the requirement for investigators to obtain a signed consent form for some or all subjects. An investigator must complete the appropriate form and submit it to the IRB for approval, if they wish to alter consent, waive the requirement to obtain consent or waive the requirement for a signed consent.

Assent of Children and Permission by Parents:

IRB shall determine that adequate provisions are made for soliciting the assent of children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children 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 to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived.

The federal regulations do not specify the age at which written assent from children is required. For children who are too young to read and sign an assent form, but who would be capable of understanding an oral explanation, an oral explanation can be provided. Investigators should remember that the assent process should take into account, in both oral and written communication, the child's age, maturity and level of understanding. The assent form does not replace a thoughtful discussion with the child regarding participation in the research. Ultimately, the assent process should illustrate respect for the child and convey the essential information the child requires, in a manner the child can understand, in order to make a decision about participating in the research.

The IRB may find that the permission of one parent is sufficient for research not involving greater than minimal risk or research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. For the following research, both parents must give their permission, unless one parent is deceased, unknown, incompetent, or not

reasonably available, or when only one parent has legal responsibility for the care and custody of the child: 1) research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition; and 2) research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

If the IRB determines that a research 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 (for example, neglected or abused children), it may waive the consent requirements, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

E. Effective Date
1993

F. Endorsed By
University Senate - 1993

G. Approved by
University President - 1993

H. Last Revised
October, 2008
February, 2011

I. Last Review
August, 2011
August, 2012
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Further information regarding the protection of human subjects can be found in the Code of Federal Regulations, 45 CFR 46.