

Policy and Procedure Regarding Use of Human Subjects in Research

1. GENERAL GUIDELINES

The American University in Cairo complies with regulations of the Department of Health and Human Services for the protection of human subjects involved in research (45 CFR 46 as amended and published in the Federal Register on June 18, 1991). AUC applies the principles of protection of human subjects whether or not the research is subject to US regulations or conducted using funding supplied by agencies of the US government.

The AUC Institutional Review Board for the Protection of Human Subjects (IRB) is charged with the responsibility of reviewing, prior to its initiation, all research involving human subjects (whether or not funded). The IRB is concerned with justifying the participation of subjects in research and protecting the welfare, rights and privacy of subjects. The IRB is composed of seven members: five from the AUC, and one external community member. Members must be from varying backgrounds and disciplines, and must include both men and women. At least one member must have a primary career base in science and one should be primarily concerned with non-science areas. The members of the IRB will be appointed by the Provost. They will in so far as possible serve during two or more academic years. Institutional support for the work of the IRB is provided by the IRB chair. The IRB will have the capacity to add individuals to its ranks as needed on a case-by-case basis to ensure its ability to review proposed research projects fully. Interested parties may obtain the names and qualifications of the current members of the IRB by request to the Office of the Provost.

All research (including interviews, surveys, and questionnaires) involving humans as subjects must be reviewed by the IRB. Provisional approval may be granted by the IRB as needed during the design of a project or preparation of a proposal. Full approval must be sought as soon as feasible, and must be obtained before the involvement of human subjects in the project begins.

Students making proposals must specify the name of an AUC faculty supervisor responsible for overseeing the research. The same holds for researchers from outside AUC who run proposals through the IRB: they too should list an AUC faculty liaison when making their proposal.

2. TYPES OF REVIEW

The IRB will review projects by one of three methods: Exempt, Expedited, and Full Board Review.

A. Exempt Review:

Certain categories of research qualify for exempt review. Exempt proposals are reviewed and certified by the Chair of the IRB, working through the Office of the Vice Provost. Please allow one week for exempt reviews. Research activities in which the only involvement of human subjects will be in one or more of the following categories qualify for review under the exempt category:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

- (a) research on regular and special education instructional strategies, or
- (b) 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:**

- (a) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; **and**
- (b) 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. (See however Section 11 below for special considerations required when children are involved.)

(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 paragraph (2) of this section, if:

- (a) The human subjects are elected or appointed public officials or candidates for public office; or
- (b) 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:

- (a) public benefit or service programs;
- (b) procedures for obtaining benefits or services under those programs;
- (c) possible changes in or alternatives to those programs or procedures; or
- (d) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Research which is conducted on a collaborative basis with one or more other institutions whose IRB has reviewed and approved the research project and AUC assists with the implementation of activities fully covered by that approval. If the AUC role results in new activity not fully covered by the collaborating institution's IRB approval, or if AUC actions require that informed consent not provided for under the procedures established by the collaborating institution, the activity is not eligible for exempt review by the AUC IRB.

(7) Taste and food quality evaluation and consumer acceptance studies,
(a) if wholesome foods without additives are consumed or
(b) 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 and approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the US Department of Agriculture. Where stricter requirements have been established by appropriate Egyptian Agencies these will be observed to ensure that safe levels are observed.

B. Expedited Review:

Expedited reviews do not require a convened meeting of the IRB. The chair of the IRB chooses a limited number of board members to review the proposal. The IRB members return their comments to the chair, who notifies the principal investigator of the results of the review. Please allow one month for an expedited review. Research activities involving no more than minimal risk and in which the only involvement of human subjects will be in one or more of the following categories may be reviewed through the expedited review procedure:

(1) Collection of: hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

(2) Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

(3) Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed at clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, the testing of sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).

(4) Acquisition of blood samples by finger pricking for collection of blood droplets or smears, from subjects 18 years of age or older and who are in good health and not pregnant.

(5) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

(6) Voice recordings made for research purposes such as investigations of speech defects.

(7) Moderate exercise by healthy volunteers.

(8) The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

(9) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

(10) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

C. Full Board Review:

The IRB schedules meetings as needed to review all proposals which do not fall into the Exempt or Expedited categories. Principal investigators may be invited to attend the meeting to discuss their proposal. Please allow one month for full board review.

3. REVIEW CRITERIA

In any review (expedited, exempt, or full board), the reviewers will determine that:

(1) Participation of human subjects in the project is justified.

(2) Risks to subjects are minimized by using appropriate procedures.

(3) Risks are justified in view of anticipated benefits.

(4) Selection of subjects is equitable. Justification is required if the subject population is restricted to one gender or ethnic group.

(5) Adequate provision is made for confidentiality of data and anonymity of participants in any published record.

(6) Adequate provision is made for the rights and welfare of participants who are mentally, physically, economically or educationally disadvantaged.

(7) Adequate provision is made for obtaining informed consent of the subjects, including those who may not be literate.

4. OBTAINING INFORMED CONSENT

Informed consent will be sought from all prospective subjects (or their legally authorized representatives) unless waived by the IRB. The IRB may waive the requirement of a signed consent form if:

(a) this consent form is the only record linking the subject with the research and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(b) the research presents no more than minimal risk of harm to subjects, involving no procedures for which written consent is normally required outside the context of the research. Such a waiver might be appropriate where the research involves minimal risk, the rights and

welfare of the subjects are not adversely affected, and the research would not be feasible without the waiver.

The waiver of a written informed consent document does not waive the need for subjects to give their informed consent. Subjects should be presented with an oral description of the research and other pertinent items from "The Basic Elements of Informed Consent."

A description of the nature of the oral presentation must be submitted to the IRB. Documented informed consent will consist of a written consent form approved by the IRB and signed by the subject or the subject's authorized representative. A copy shall be given to the person signing the form.

The signed consent forms and summaries shall be kept in the investigator's confidential file for at least three years beyond the end date of the project. The consent form may be either of the following:

(a) A written consent document that embodies the elements of informed consent. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

(b) A "short form" written consent document stating that the elements of informed consent 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."

5. BASIC ELEMENTS OF INFORMED CONSENT

The informed consent of subjects must be obtained by methods that are adequate and appropriate for the situation (see previous section). Informed consent is the agreement obtained from a subject, or from an authorized representative, for the subject's participation in an activity. The agreement, written or oral, entered into by the subject, may include no exculpatory language through which the subject is made to waive, or to appear to waive, any of the subject's legal rights, or to release the investigator, the sponsor, the institution or its agents from liability for negligence. The basic elements of informed consent are:

(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 or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; for example: "I understand the University does not provide a research subject with compensation or medical treatment in the event the subject is injured as a result of participation in the research project."

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject; for example: "Questions about the research, my rights, or research-related injuries should be directed to (PI name) at (telephone number)."

(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 that 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 additional elements of informed consent shall also be provided to each subject:

(1) A statement that a 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; and

(6) The approximate number of subjects involved in the study.

6. CONTINUING REVIEW

In its initial review of a proposal, the IRB will consider the extent of continuing review needed. All ongoing projects shall be reviewed annually, but in certain research the subjects are exposed to more than usual risk; such projects will be reviewed at more frequent intervals consistent with the research. This review interval will be determined at the time the research is approved and may be changed at the discretion of the IRB. In each such review, the principal

investigator will be required to promptly report the status of the research activity, and any proposed changes in the research activity. If the research is still in progress, the investigator will affirm that the approved research protocol involving human subjects is being followed.

7. NONCOMPLIANCE ACTION

It is the obligation of the researcher and administrative supervisors to advise the IRB of any circumstances which arise during the course of research which could result in noncompliance with this policy of the AUC or the requirements of the IRB. In any instance where IRB requirements are not being followed, the IRB shall inform the principal investigator and also the Provost, who will be asked to enforce the requirements. In the event that the principal investigator does not comply, the Provost, in consultation with the Dean or Center Director, will terminate the research. Such action will be accompanied by a letter to the principal investigator, stating the reason for the action. If unanticipated problems, including noncompliance and termination, involving risks to subjects or others occur, these will be reported to the Secretary of the Department of Health and Human Services.

8. ARBITRATION

Any matters requiring arbitration between the IRB and a principal investigator, or questions not resolved by the IRB, will be referred to the Provost. The Provost or an ad hoc committee appointed by the Provost, will meet with the Board and the principal investigator, seeking a resolution of the differences. They will report their findings to the Board and principal investigator, after which the IRB will meet again to reconsider the matter and render a decision. In no instance may any official of the institution overrule an IRB decision for disapproval.

9. RECORDS RETENTION REQUIREMENTS

All records must be retained for at least three years after completion of the research. Records may include such items as research proposals, informed consent documents, progress reports, reports of injuries to subjects, and all related correspondence concerning the use of human subjects.

10. PREPARATION INSTRUCTIONS

All materials required by the IRB, including proposal and the AUC proposal application form should be submitted to the Office of the Associate Provost for Research Administration. All materials constituting the informed consent documents should use lay language and be prepared in a manner which will facilitate effective communication with those providing the consent.

11. ADDITIONAL PROTECTIONS FOR SPECIAL POPULATIONS OF SUBJECTS

A. Fetuses, Pregnant Women, and Human In Vitro Fertilization

General limitations. No activity may begin unless:

(1) appropriate studies on animals and non-pregnant individuals have been completed;

(2) except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity;

(3) individuals engaged in the activity will have no part in

- (i) any decisions as to the timing, method, and procedures used to terminate the pregnancy, and
- (ii) determining the viability of the fetus at the termination of the pregnancy; and

(4) no procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity. No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

Activities directed toward pregnant women as subjects:

No pregnant woman may be involved as a subject in an activity unless:

(1) the purpose of the activity is to meet the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or (2) the risk to the fetus is minimal.

A pregnant woman may be involved as a subject in an activity only if she and the fetus's father are legally competent and have given their informed consent after having been fully informed regarding possible impact on the fetus, except that the father's informed consent need not be secured if:

(1) the purpose of the activity is to meet the health needs of the mother;

(2) his identity or whereabouts cannot reasonably be ascertained;

(3) he is not reasonably available.

Activities directed toward fetuses in utero as subjects: no fetus in utero may be involved as a subject in any activity unless:

(1) the purpose of the activity is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or

(2) the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

An activity permitted under this section may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's consent need not be secured if:

(1) his identity or whereabouts cannot reasonably be ascertained,

(2) he is not reasonably available. Activities directed toward fetuses ex utero, including nonviable fetuses, as subjects:

Until it has been ascertained whether or not a fetus ex utero is viable, a fetus ex utero may not be involved as a subject in an activity unless:

(1) there will be no added risk to the fetus resulting from the activity, and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or

(2) the purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.

No nonviable fetus may be involved as a subject in an activity unless:

(1) vital functions of the fetus will not be artificially maintained,

(2) experimental activities which of themselves would terminate the heartbeat or respiration of the fetus will not be employed, and

(3) the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.

In the event the fetus ex utero is found to be viable, it may be included as a subject in the activity only to the extent permitted by and in accordance with the requirements of other parts of this section.

An activity may be conducted only if the mother and father are legally competent and have given their informed consent, except that the father's informed consent need not be secured if:

(1) his identity or whereabouts cannot reasonably be ascertained,

(2) he is not reasonably available.

Activities Involving the Dead Fetus, Fetal Material, or the Placenta Activities involving the dead fetus, mascerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable local laws regarding such activities.

B. Prisoners

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is AUC policy to avoid use of prisoners as research subjects. Where this cannot be avoided additional safeguards must be provided for the protection of prisoners involved in research. In this event Principal Investigators must contact the IRB through the Office of the Vice Provost to obtain guidance in regard to development of the research plan and the special requirements of the IRB for such cases.

C. Children

To What Does This Section Apply?

The categories of research listed as "exempt" beginning on page 1 of this Handbook are generally applicable. However the exemption for research involving survey or interview procedures or observations of public behavior does not apply to research involving children, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

Definitions

"Children" are 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.

"Assent" means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

"Permission" means the agreement of parent(s) or guardian to the participation of their child or ward in research.

"Parent" means a child's biological or adoptive parent.

"Guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

Research Not Involving Greater than Minimal Risk

The IRB will approve projects in which no greater than minimal risk to children is presented, only if adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.

Research Involving Greater than Minimal Risk but Presenting the Prospect of Direct Benefit to the Individual Subjects

The IRB will approve projects in which more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if:

- (1) the risk is justified by the anticipated benefit to the subjects;
- (2) the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
- (3) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

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

The IRB will approve projects in which more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual

subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if:

- (1) the risk represents a minor increase over minimal risk;
- (2) the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- (3) the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and
- (4) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

Research Not Otherwise Approvable which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Children

The IRB will approve projects in this category only if:

- (1) the IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and
- (2) when DHHS funding is sought, the Secretary of DHHS, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:
 - (a) that the research satisfies the conditions of the above categories, or
 - (b) the following:
 - (i) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
 - (ii) the research will be conducted in accordance with sound ethical principles;
 - (iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

Requirements for Permission by Parents or Guardians and for Assent by Children

The IRB shall determine that adequate provisions are made for soliciting the assent of the 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 in accordance with general informed consent provisions.

In addition, the IRB shall determine that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that permission of one parent is sufficient for research involving minimal risk or for research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. For research involving greater risk and no prospect of direct benefit to subjects, permission is to be obtained from both parents, 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.

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.

Permission by parents or guardians shall be documented.

When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

Wards

Children who are wards of the State or any other agency, institution, or entity can be included in research only if such research is:

- (1) related to their status as wards; or
- (2) conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the research is approved, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

(Note: All queries related to this Policy may be directed to the Chair of the Institutional Review Board for the Protection of Human Subjects at irb@aucegypt.edu)