



EL PASO COMMUNITY COLLEGE PROCEDURE

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2.03.01.22 Procedure for the Protection of Human Subjects Participating in El Paso Community College Research Programs

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AUTHORIZING BOARD POLICY: 2.03.01

Classification: Administrative

Responsible Vice President or Associate Vice President: Vice President of Research, Accreditation and Planning

Designated contact: Director of Institutional Research

OBJECTIVE: To provide a process for the protection of human subjects participating in El Paso Community College (EPCC) Research Programs. The process is an adaptation of the basic DHHS policy for protection of human research subjects. The DHHS policy was published in the Code of Federal Regulations Title 45 Part 46 (45CFR46). Anyone wishing to conduct research on human subjects should be familiar with 45CFR46. In addition, this procedure specifies absolute standards of ethical principles and conduct for EPCC Research Programs. The standards are contained in the Nuremberg Code, The Declaration of Helsinki, and The Belmont Report. EPCC staff and faculty who are involved with research involving human subjects must be familiar with these principles and standards, and operate their programs accordingly.

PROCEDURE:

PART A

I. DEFINITIONS

- A. *Sponsor Department or Agency Head* means the head of any sponsor Department or Agency and/or any other officer or employee of any Department or Agency to whom authority has been delegated.
- B. *Institution* means any public or private entity or Agency (including Federal, State, and other agencies).
- C. *Legally authorized representative* means an individual, or judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research.
- D. *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
- E. *Research subject to regulation*, and similar terms are intended to encompass those research activities for which a Federal Department or Agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a Federal Department or Agency solely as part of the Department’s or Agency’s broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).
- F. *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains:
 - 1. data through intervention or interaction with the individual; or
 - 2. identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

- G. *IRB* means an Institutional Review Board established in accord with and for the purposes expressed in this procedure.
- H. *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at EPCC within the constraints set forth by the IRB and by other institutional and Federal requirements.
- I. *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- J. *Certification* means the official notification by EPCC to the supporting Department or Agency, in accordance with the requirements of this procedure, that a research project or activity involving human subjects has been reviewed and approved by our IRB in accordance with an approved assurance.

II. TO WHAT DOES THIS PROCEDURE APPLY?

- A. This procedure applies to all research involving human subjects including all surveys, focus groups and formal interviews.

Research that is supported by a Sponsor Department or Agency, whether or not it is regulated as defined in 45CFR46, must be reviewed and approved by an Institutional Review Board (IRB) that operates in accordance with the pertinent requirements of 45CFR46.

- B. Unless otherwise required by Sponsor Department or Agency Heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this procedure but must be reviewed by the Institutional Review Board to establish the exemption:
 - 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 subject's 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 paragraph B2 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.
 - 4. Research involving the collection or study of existing data, documents, records, pathological 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 subject to the approval of Sponsor 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: (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.
- C. The EPCC Institutional Review Board in conjunction with any Sponsor Department or Agency Head retains final judgment as to whether a particular activity is covered by this procedure.
 - D. Sponsor Department or Agency heads may require that specific research activities or classes of research activities supported, otherwise subject to regulation by the Sponsor Department or Agency but not otherwise covered by 45CFR46, comply with some or all of the requirements of this procedure.
 - E. Compliance with this procedure requires compliance with pertinent Federal laws or regulations which provide additional protections for human subjects.
 - F. This procedure does not affect any State or local laws or regulations which may otherwise be applicable and which provide additional protections to human subjects.
 - G. This procedure does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects or research.

III. GENERAL PROCEDURES AND PRINCIPLES

- A. El Paso Community College Research programs will be governed by ethical principles that protect the human subjects participating in these programs. The ethical principles and conduct stated in the Nuremberg Code, The Declaration of Helsinki, and the Belmont Report will be absolute standards of program design and operation.
- B. The Vice President for Research, Accreditation, & Planning in coordination with the Director of Institutional Research, has established the IRB to fulfill the duties required to protect human subjects. Provisions for meeting space and support staff are to be made to ensure the IRB's effective performance of their duties.
- C. The Director of Institutional Research maintains a list of IRB members identified by name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, paid or unpaid consultant.
- D. The Director of Institutional Research
 1. reviews all applications to conduct research on humans and forwards them to the Chair of the IRB. The applicant(s) must complete the **El Paso Community College Application for Permission to use Human Subjects in Research** (attached).
 2. Determines which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since a previous IRB review; and
 3. Ensures prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject.

- E. The Director of Institutional Research ensures prompt reporting to the IRB, appropriate institutional officials, and the Department or Agency Head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.

IV. IRB MEMBERSHIP

- A. Each IRB shall have at least 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. The IRB shall therefore include persons knowledgeable in these areas.

If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

- B. Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
- C. Each 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.
- D. Each IRB shall include at least one member 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.
- E. No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has conflicting interest, except to provide information requested by the IRB.
- F. 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.

V. IRB FUNCTIONS AND OPERATIONS

In order to fulfill the requirements of this procedure, each IRB shall:

- A. follow written procedures in the same detail as described in this Section IIID and to the extent required by this Section III E; and
- B. except when an expedited review procedure is used (see Section VII), review proposed research at 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.

VI. IRB REVIEW OF RESEARCH

- A. IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.
- B. The IRB shall require that information given to subjects as part of informed consent is in accordance with Section VIII. The IRB may require that information, in addition to that specifically mentioned in this Section VIII, be given to the subjects when in the IRB's judgment the information would meaningfully add to the protection of the rights and welfare of subjects.

- C. The IRB shall require documentation of informed consent or may waive documentation in accordance with this Section XIV.
- D. The IRB shall notify investigators and the institution in writing of its decision to approve or disapprove the proposed research activity, or to 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.
- E. The IRB shall conduct continuing review of research covered by this policy 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.

VII. EXPEDITED REVIEW PROCEDURES FOR CERTAIN KINDS OF RESEARCH INVOLVING NO MORE THAN MINIMAL RISK, AND FOR MINOR CHANGES IN APPROVED RESEARCH

- A. The Secretary, HHS, has established as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure. The list will be amended, as appropriate, after consultation with other departments and agencies, through periodic republication by the Secretary, HHS, in the Federal Register. A copy of the list is available from the Office for Protection from Research Risks, National Institutes of Health, DHHS, Bethesda, Maryland 20892. For information relevant to other sponsoring departments or agencies communicate with their research protocol office.
- B. An IRB may use the expedited review procedure to review either or both of the following:
 - 1. some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk; and/or
 - 2. minor changes in previously approved research during the period (of one year or less) for which approval is authorized.

Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review in accordance with non-expedited procedure set forth in this Section VB.

- C. If the IRB uses an expedited review procedure it will adopt a method of keeping all members advised of research proposals which have been approved under the procedure.
- D. The Sponsor Department or Agency head may restrict, suspend, terminate, or choose not to authorize an institution's or IRB's use of the expedited review procedure.

VIII. CRITERIA FOR IRB APPROVAL OF RESEARCH

- A. In order to approve research covered by this procedure the IRB shall determine that all of the following requirements are satisfied:
 - 1. risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes;
 - 2. risks to subjects are reasonable in relation to: (i) anticipated benefits, if any, to subjects, and (ii) the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility;
 - 3. 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;

4. informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by this Section XIII;
 5. informed consent will be appropriately documented, in accordance with, and to the extent required by this Section XIV;
 6. when appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subject; and
 7. when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
- B. When some or all of the subjects are likely to be vulnerable to 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.

IX. REVIEW BY INSTITUTION

Research covered by this procedure that has been approved by an IRB will be subject to further appropriate review and approval or disapproval by the Vice President for Research, Accreditation, & Planning. However, the Vice President may not approve the research if it has not been approved by an IRB.

X. SUSPENSION OR TERMINATION OF IRB APPROVAL OF RESEARCH

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination or approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, the Vice President for Research, Accreditation, & Planning and the Department or Agency Head.

XI. COOPERATIVE RESEARCH

Cooperative research projects are those projects covered by this procedure which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this procedure. With the approval of the Sponsor Department or Agency Head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

XII. IRB RECORDS

- A. When appropriate, the IRB will prepare and maintain adequate documentation of IRB activities, including the following:
1. 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 injuries to subjects;
 2. 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 controversial issues and their resolution;
 3. records of continuing review activities;
 4. copies of all correspondence between the IRB and the investigators;
 5. a list of IRB members in the same detail as described in Section IIIC;
 6. written procedures for the IRB in the same detail as described in this Section IIID and IIIE; and

7. statements of significant new findings provided to subjects, as required by this Section XIII B5;
- B. The IRB records will be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the Sponsoring Department or Agency at reasonable times and in a reasonable manner.

XIII. GENERAL REQUIREMENTS FOR INFORMED CONSENT

Except as provided elsewhere in this procedure, no investigator may involve a human being as a subject in research covered by this procedure unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized 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. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

- A. Basic elements of informed consent. Except as provided in paragraph C or D of this section, in seeking informed consent the following information shall be provided to each subject:
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 subject's rights, and whom to contact in the event of a research-related injury to the subject; and
 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.
- B. Additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:
1. 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; and
 6. the approximate number of subjects involved in the study.
- C. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:
1. the research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is 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; and
 2. the research could not practicably be carried out without the waiver or alteration.
- D. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
1. the research involves no more than minimal risk to the subjects;
 2. the waiver or alteration will not adversely affect the rights and welfare of the subjects;
 3. the research could not practicably be carried out without the waiver or alteration; and
 4. whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- E. The informed consent requirements in this procedure are not intended to preempt any applicable Federal, State, or local laws which require additional information to be disclosed in order for consent to be legally effective.
- F. Nothing in this procedure is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable Federal, State, or local law.

XIV. DOCUMENTATION OF INFORMED CONSENT

- A. Except as provided in paragraph C of this section, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.
- B. Except as provided in paragraph C of this section, the consent form may be either of the following:
1. a written consent document that embodies the elements of informed consent required by Section XIII. 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
 2. a short form written consent document stating that the elements of informed consent required by Section XIII 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.

- C. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:
1. that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
 2. that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

PART B

- I. The regulations in this part of the EPCC procedure provide additional protections for pregnant women, fetuses, and human *in vitro* fertilization. All EPCC sponsored programs conducting research, development, and related activities with the subjects stated above must comply with these regulations except where exempt (see Part A-IIB).

II. DEFINITIONS

As used in this subpart:

- A. *Secretary* means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services (DHHS) to whom authority has been delegated.
- B. *Pregnancy* encompasses the period of time from confirmation of implantation (through any of the presumptive signs of pregnancy, such as missed menses, or by a medically acceptable pregnancy test), until expulsion or extraction of the fetus.
- C. *Fetus* means the product of conception from the time of implantation (as evidenced by any of the presumptive signs of pregnancy, such as missed menses, or a medically acceptable pregnancy test), until a determination is made, following expulsion or extraction of the fetus, that it is viable.
- D. *Viable* as it pertains to the fetus means being able, after either spontaneous or induced delivery, to survive (given the benefit of available medical therapy) to the point of independently maintaining heart beat and respiration. The Secretary may from time to time, taking into account medical advances, publish in the Federal Register guidelines to assist in determining whether a fetus is viable for purposes of this subpart. If a fetus is viable after delivery, it is a premature infant.
- E. *Nonviable fetus* means a fetus *ex utero* which, although living, is not viable.
- F. *Dead fetus* means a fetus *ex utero* which exhibits neither heartbeat, spontaneous respiratory activity, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord (if still attached).
- G. *In vitro fertilization* means any fertilization of human ova which occurs outside the body of a female, either through admixture of donor human sperm and ova or by any other means.

III. ADDITIONAL DUTIES OF THE INSTITUTIONAL REVIEW BOARDS IN CONNECTION WITH ACTIVITIES INVOLVING FETUSES, PREGNANT WOMEN, OR HUMAN IN VITRO FERTILIZATION

- A. In addition to the responsibility prescribed for Institutional Review Boards under Part A above, the IRB shall, with respect to activities covered by Part B, carry out the following additional duties:
1. determine that all aspects of the activity meet the requirements of Part B;
 2. determine that adequate consideration has been given to the manner in which potential subjects will be selected, and adequate provision has been made by the applicant for monitoring the actual informed consent process (e.g., through such mechanisms, when appropriate, as participation by the Institutional Review Board or subject advocates in: (i) overseeing the actual process by which individual consents required by this subpart are secured either by approving induction of each individual into the activity

or verifying, perhaps through sampling, that approved procedures for induction of individuals into the activity are being followed, and (ii) monitoring the progress of the activity and intervening as necessary through such steps as visits to the activity site and continuing evaluation to determine if any unanticipated risks have arisen); and

3. carry out such other responsibilities as may be assigned by the Secretary.
- B. No award may be issued until the applicant has certified to the Secretary that the Institutional Review Board has made the determinations required under paragraph A of this section and the Secretary, HHS, has approved these determinations, as provided in 46.120 of 45CFR46 (Code of Federal Regulations).
- C. Applicants seeking support for activities covered by Part B must provide for the designation of an Institutional Review Board, subject to approval by the Secretary, where no such Board has been established under Part A.

IV. GENERAL LIMITATIONS

- A. No activity to which Part B is applicable may be undertaken 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.
- B. No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

V. ACTIVITIES DIRECTED TOWARD PREGNANT WOMEN AS SUBJECTS

- A. No pregnant woman may be involved as a subject in an activity covered by Part B 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.
- B. An activity permitted under paragraph A of this section may be conducted only if the mother and 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; or
 4. the pregnancy resulted from rape.

VI. ACTIVITIES DIRECTED TOWARD FETUSES *IN UTERO* AS SUBJECTS

- A. No fetus *in utero* may be involved as a subject in any activity covered by this subpart 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.
- B. An activity permitted under paragraph a of 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; or
 3. the pregnancy resulted from rape.

VII. ACTIVITIES DIRECTED TOWARD FETUSES *EX UTERO*, INCLUDING NONVIABLE FETUSES, AS SUBJECTS

- A. 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 covered by Part B 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.
- B. No nonviable fetus may be involved as a subject in an activity covered by Part B 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.
- C. 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 sections of Part B.
- D. An activity permitted under paragraph A or B of 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 informed consent need not be secured if:
1. his identity or whereabouts cannot reasonably be ascertained;
 2. he is not reasonably available; or
 3. the pregnancy resulted from rape.

VIII. ACTIVITIES INVOLVING THE DEAD FETUS, FETAL MATERIAL, OR THE PLACENTA

Activities involving the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.

PART C

- I.** The regulations in Part C are applicable to all EPCC programs conducting biomedical and behavioral research involving prisoners as subjects. Following the procedures set forth herein does not authorize research involving prisoners when applicable State or local law limit or bar such activities.

II. PURPOSE

In as much as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary decision regarding whether or not to participate as subjects in research it is the purpose of this

subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

III. DEFINITIONS

As used in Part C:

- A. *Sponsor Department or Agency Head* means the Head of any Sponsor Department or Agency and any other officer or employee of the Sponsor Department or Agency to whom authority has been delegated.
- B. *Sponsor Department or Agency* means the Federal Department or Agency that funds all or part of an EPCC Research program.
- C. *Prisoner* means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.
- D. *Minimal risk* is 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.

IV. COMPOSITION OF INSTITUTIONAL REVIEW BOARDS WHERE PRISONERS ARE INVOLVED

In addition to satisfying the requirements in Part A-IV, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

- A. A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, a part from their membership on the Board.
- B. At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need to satisfy this requirement.

V. ADDITIONAL DUTIES OF THE INSTITUTIONAL REVIEW BOARDS WHERE PRISONERS ARE INVOLVED

- A. In addition to all other responsibilities prescribed for Institutional Review Boards under Part C, the Board shall review research covered by this subpart and approve such research only if it finds that:
 - 1. the research under review represents one of the categories of research permissible under Part C;
 - 2. 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;
 - 3. the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
 - 4. procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
 - 5. the information is presented in language which is understandable to the subject population;
 - 6. 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; and

7. where the Board 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.
- B. The Board shall carry out such other duties as may be assigned by the Sponsor Department or Agency Head.
 - C. The institution shall carry to the Sponsor Department or Agency Head, in such form and manner as the Department or Agency Head may require, that the duties of the Board under this section have been fulfilled.

VI. PERMITTED RESEARCH INVOLVING PRISONERS

- A. Biomedical or behavioral research conducted or supported by the Sponsoring Department or Agency may involve prisoners as subjects only if:
 1. the institution responsible for the conduct of the research has certified to the Sponsor Department or Agency Head that the Institutional Review Board has approved the research under Part C -V; and
 2. in the judgment of the Department or Agency Head the proposed research involved solely the following: (i) study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects, (ii) study of prisoners 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, (iii) research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Department or Agency Head has consulted with appropriate experts including experts in penology, medicine, and ethics and published notice, in the Federal Register, of his intent to approve such research, or (iv) research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Department or Agency Head has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.
- B. Except as provided in paragraph A of this section, biomedical or behavioral research conducted or supported by Department of Health and Human Services shall not involve prisoners as subjects.

PART D

- I. The procedures in Part D apply to all EPCC Research programs funded by a sponsoring department or agency that involves children as subjects.
 - A. Exemptions at Part A-II B1 and B3 through B6 are applicable to this subpart. The exemption at Part A-II B2 regarding educational tests is also applicable to this subpart. However, the exemption at Part A-II B2 for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.
 - B. The exceptions, additions, and provisions for waiver as they appear in paragraphs C through I of Part A-II are applicable to this subpart.

II. DEFINITIONS

The definitions in Part A-I shall be applicable to this subpart as well. In addition, as used in this subpart:

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

- C. *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.
- D. *Parent* means a child's biological or adoptive parent.
- E. *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

III. IRB DUTIES

In addition to other responsibilities assigned to IRB's under this part, each IRB shall review research covered by this subpart and approve only research which satisfies the conditions of all applicable sections of this subpart.

IV. RESEARCH NOT INVOLVING GREATER THAN MINIMAL RISK

Sponsoring Departments or Agencies will fund research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in Section VII.

V. RESEARCH INVOLVING GREATER THAN MINIMAL RISK BUT PRESENTING THE PROSPECT OF DIRECT BENEFIT TO THE INDIVIDUAL SUBJECTS

DHHS will conduct or fund research in which the IRB finds that 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 the IRB finds that:

- A. the risk is justified by the anticipated benefit to the subject;
- B. 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
- C. adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in this subpart VII.

VI. RESEARCH INVOLVING GREATER THAN MINIMAL RISK AND NO PROSPECT OF DIRECT BENEFIT TO INDIVIDUAL SUBJECTS, BUT LIKELY TO YIELD GENERALIZABLE KNOWLEDGE ABOUT THE SUBJECTS DISORDER OR CONDITION

DHHS will conduct or fund research in which the IRB finds that 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 the IRB finds that:

- A. the risk represents a minor increase over minimal risk;
- B. 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;
- C. 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
- D. adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in this Section VII.

VII. REQUIREMENTS FOR PERMISSION BY PARENTS OR GUARDIANS AND FOR ASSENT BY CHILDREN

- A. In addition to the determinations required under other applicable sections of this subpart, 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 accord with Part A-XIII.

- B. In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by Part A-XIII, 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 to be conducted under Section IV or V. Where research is covered by Section VI and permission is to be obtained from parents, 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.
- C. In addition to the provisions for waiver contained in Part A-XIII, 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 in Subpart A of this part and paragraph B of this section, 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.
- D. Permission by parents or guardians shall be documented in accordance with and to the extent required by Part A-XIV.
- E. When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

VIII. WARDS

- A. Children who are wards of the State or any other agency, institution, or entity can be included in research approved under Section VI 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.
- B. If the research is approved under paragraph A of this section, 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.



**EI PASO COMMUNITY COLLEGE
APPLICATION FOR PERMISSION TO USE HUMAN SUBJECTS IN RESEARCH
APPROVAL IS VALID FOR ONE YEAR FROM APPROVAL DATE**

See College Procedure 2.03.01.22: *Procedure for the Protection of Human Subjects Participating in El Paso Community College Research Programs.*

THIS FORM MUST BE TYPED FOR PROCESSING – DO NOT LEAVE ANY BLANKS. (Please refer to definitions on pages 1, 2 and 18.)

Principal Investigator(s) _____ Phone _____ Date _____

Institution _____ Department _____

Title of Research Project _____

Please check purpose of project: _____ Master's Thesis _____ Doctoral Dissertation _____ Class Assignment

Other (explain): _____

Name of faculty advisor (if any): _____

Where will work be done? _____

When will the research begin? _____ When will the research end? _____

CHECKLIST FOR RESEARCHER

Please check appropriately. If explanation is needed, use the back of the form and additional sheets if necessary.

YES NO

GENERAL ISSUES

1. _____ Are federal funds involved? If yes, sponsor's name: _____ **(please explain on back)**
2. _____ Other external funds? If yes, sponsor's name: _____
3. _____ Is application a renewal application for same research done one or more years ago and previously by this committee?
4. _____ Do you have any financial conflict of interest? **(If yes, please explain on back)**
5. _____ Will this project require the supervision of a physician? **(If yes, please explain on back)**

SUBJECT RELATED ISSUES

6. _____ Has the selection of subjects been equitable, with particular recognition of the special problems of research involving vulnerable populations such as women, children, prisoners, mentally disabled persons or economically or educationally disadvantaged persons? **(If no, please explain on back)**
7. _____ Are subjects minors or have diminished mental or physical capability? **(If yes, please explain on back)**
8. _____ Subjects have been given a choice of the following: participate or do another assignment (i.e., book review, paper, etc.)
9. _____ Subjects have been offered one or more of the following incentives to participate in the research: money, extra credit for the class **(If yes, please explain on back).**
10. _____ Subjects will be allowed to participate in the research during regularly scheduled class time.

INFORMED CONSENT/ASSENT ISSUES

11. _____ Will each subject be fully informed?
12. _____ Will each subject be debriefed following completion of the research?
13. _____ Will each subject's personal privacy be protected? **(If no, please explain on back)**
14. _____ Will each subject, prior to the research, indicate informed consent/assent to participate by completing and signing a written form **(If no, please explain on back) (copy of informed consent form must be attached to this application)** which includes:
 - a. A description of the potential risks to the subjects including physical, psychological, emotional, social or spiritual wellbeing,
 - b. A description of how the personal privacy of the subject will be protected,
 - c. A description of any incentives for the subjects and restrictions for receiving such incentives,
 - d. An indication that the subjects' participation is entirely voluntary and that they may withdraw at any time, and
 - e. A description of any debriefing that will be made available to the subjects?

If items 1, 4, 5, 7, 9 are checked YES, please explain on back; if items 6, 13, 14 are checked NO please explain on back.

PROTOCOL OF RESEARCH PROJECT

Provide the following information: brief description of research methods, time required for single session, number of sessions, psychological or medical methods to be used, research objectives or hypothesis(es); if a survey instrument or other interview protocol is to be used, please attach a copy.

SUBJECTS: Number of Subjects _____ **Age of Subjects** Over 18 _____ Under 18 _____
If under 18, please indicate ages _____
Sex of Subjects _____ Male _____ Female _____ Both _____

SAFETY MEASURES: Outline specific safety controls. If applicable, indicate what OSHA requirements will be observed. If applicable, indicate what universal standards will be observed. If subjects are minors and/or have diminished mental capability and/or have diminished physical capability, indicate special precautions that will be observed. If physician’s attendance is necessary, explain why.

PHYSICIAN’S NAME AND CONTACT INFORMATION (If Physician’s attendance is necessary)

EXPLANATIONS FOR CHECKLIST RESPONSES (MANDATORY FOR #1, 4, 5, 7, 9 if checked YES; #6, 13, 14 if checked NO)

Faculty Advisor Approval Signature (if applicable) _____ **Date:** _____

Division or Dept. Head Approval Signature _____ **Date:** _____

I have read the EPCC Administrative Policies and Procedures Manual on “Human Subjects in Research” and I certify that my proposed research is in conformity with the College policy. I certify I have read the Belmont Report, the regulations for the protection of human subjects (45 CFR 46), the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research (Federal Register, March 29, 1994, pages 14508-14513), and the NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects. Copies available in College Research Center and on the Office for Human Research Protections web page at <http://ohrp.osophs.dhhs.gov/polasur.htm>.

SIGNATURE OF RESEARCHER(S) _____ **DATE** _____

DISPOSITION BY: EPCC IRB
____ Approved _____ Disapproved Chair’s Signature _____ DATE _____ Approval # _____
Forward to: EPCC Institutional Review Board (IRB), ASC, Room A-830, Office Phone Number (915) 831-6726