

ASSURANCE OF PROTECTION OF HUMAN RESEARCH SUBJECTS

University Procedure 15.99.01.C1.01—Revised March 7, 2005

1. GENERAL

- 1.1 Texas A&M University-Corpus Christi has a responsibility to protect the rights and welfare of prospective research subjects and to provide a favorable climate for the conduct of scientific inquiry. In compliance with federal regulations, the University requires all research involving human subjects to be approved by the Texas A&M University-Corpus Christi Institutional Review Board (IRB).
- 1.2 Researchers seeking approval for projects may obtain the appropriate forms from the IRB Chair, an IRB member, or the Office of Sponsored Programs.
- 1.3 This document shall automatically be updated to comply with changes in federal regulations. Other changes will go through the regular University review process.
- 1.4 The Chair of the IRB will report to the Provost and Vice President for Academic Affairs in January of each year as to the adequacy of this document and such other matters that should be brought to the attention of the faculty related to this document.

2. SCOPE OF INSTITUTIONAL REVIEW BOARD

All activities involving research with human subjects in all fields of University activity shall come under the purview of the Institutional Review Board. This committee has the primary responsibility for maintaining ethical standards of research involving human subjects at the University. All projects will be reviewed at least annually. The IRB has authority to approve or disapprove such research. It may require modifications as a condition for approval. Following the review of the research, the IRB will notify the investigators and the institution in writing of its decision. If the IRB decides to disapprove a research activity, it will provide the reasons for its decision and give the investigator an opportunity to respond in person or in writing. Federal regulations require the IRB to conduct continuing review of approved research at intervals appropriate to the degree of risk, but not less than once per year. The IRB has authority to observe or have a third party observe the consent process and the research.

3. ETHICS

3.1 TAMU-CC will use the following documents as guides for the conduct of human subject research:

- (1) the World Medical Association’s “Declaration of Helsinki”
- (2) the American Psychological Association’s statement, “Ethical Principles in the Conduct of Research with Human Participants,”
- (3) the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and
- (4) the Code of Federal Regulations, 45 CFR 46, Protection of Human Subjects.

3.2 The subjects have recourse to the IRB at any time through its Chairperson, if they feel they have not been dealt with fairly. Copies of this document and those listed above will be available for the investigator, as well as any other interested persons, upon request to the Office of the Provost/Vice President for Academic Affairs or the offices of the Deans. These materials are also available from the Office of Sponsored Programs.

4. MEMBERSHIP OF THE IRB

4.1 The membership of the IRB shall be composed of a member of the Ethics Council, two faculty members from each of the Colleges, a representative from the Library, and two persons from the community. All members are voting members. The faculty members are appointed by the process described in “University Committees and University Councils.” The community members are appointed by the President or the President’s designee. In addition, the committee make-up will reflect the guidelines established in the Code of Federal Regulations, 45 CFR 46, section 46.107, titled IRB membership. As stated in the guidelines, the membership will include persons of varying backgrounds to promote complete and adequate review of research activities commonly conducted by the University. The members will have expertise and experience in a variety of specified areas. Also, the membership should reflect diversity, including consideration of race, gender, and cultural backgrounds and sensitivity to community attitudes. (For more information, see 45 CFR 46.)

4.2 Terms of membership for faculty members shall be three years on an alternating basis. The community members shall serve two-year terms. The Ethics Council member will have a re-appointable, three-year term. The Chairperson of the IRB shall be elected from within the membership of the IRB for a two-year term by the IRB and shall be eligible for re-election. A vice chair will also be elected for a two-year term from within the membership of the IRB. A member of the IRB will be elected by the committee to serve a one-year term as secretary.

5. MEETINGS OF THE IRB

The IRB shall meet monthly during the two regular semesters and at the call of the Chair. A quorum shall be a simple majority. The IRB may establish its own operating procedures within these prescribed guidelines. Projects for review at its monthly meeting shall be received at least 10 working days prior to its monthly meeting.

6. CRITERIA FOR APPROVING RESEARCH

To be approved by the IRB, human subjects research which is covered by federal policy must meet all the following criteria:

- (1) risks to subjects are minimized by using procedures that are consistent with sound research design and whenever appropriate, use procedures already being performed on the subjects for diagnostic or treatment purposes;
- (2) risks to subjects are reasonable in relation to anticipated benefits to subjects, and the importance of the knowledge that may reasonably be expected to result;
- (3) selection of subjects is equitable in terms of the purposes of the research and the setting in which it will be conducted;
- (4) informed consent is sought from each prospective subject and documented to include all appropriate information;
- (5) the protocol makes adequate provision for monitoring the data collected to ensure the safety of the subjects;
- (6) adequate provision is made and documented to protect the privacy of subjects and to maintain the confidentiality of the data; and
- (7) where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate safeguards have been included in the study to protect their rights and welfare.

7. RESEARCH REVIEW CATEGORIES

The extent of the IRB review will depend upon the nature of the research. There are three research review categories: exempt research, expedited review, and full review.

7.1 Exempt Research

7.1.1 Certain categories of research are exempt from the Protection of Human Subjects policy in the Code of Federal Regulations 45 CFR 46. The IRB Chair will determine, based on the federal guidelines, whether a research activity qualifies for exemption. Although exempt research is not regularly reviewed by the IRB, the exempt research form (and the informed consent form, if applicable) must be on file with the IRB, and the research may be reviewed at the committee's discretion. If the committee deems necessary, it may require a full review.

7.1.2 Unless otherwise required by federal departments or agencies, research activities in which the only involvement of human subjects will be in one or more of the following categories are generally exempt from full review by the IRB:

- (1) Research conducted in established or commonly accepted educational settings, involving normal education 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 human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the previous paragraph, if:
 - (i) the human subjects are elected or appointed public officials or candidates for public office; or
 - (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (5) Research and demonstration projects that are conducted by or subject to the approval of federal department or agency heads, and that are designed to study, evaluate, or otherwise examine:
 - (i) public benefit or service programs;
 - (ii) procedures for obtaining benefits or services under these 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.

7.1.3 Research involving special or protected populations, such as children, the elderly, prisoners, pregnant women, and the handicapped, is subject to full review.

7.2 Expedited Review

7.2.1 Expedited review procedures are available for certain kinds of research involving no more than minimal risk, and for minor changes in approved research. Specifically, research is eligible for expedited review if it involves no more than minimal risk (see 45 CFR as amended) to the subjects and the only involvement of human subjects will be in one or more of the categories listed below:

- (1) Collection of: hair and nail clippings, in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
- (2) Collection of excreta and external excretion 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 in 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 the 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, testing sensory acuity, electro-cardiography, 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) Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older 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 recording made for research purposes such as investigation of speech defects.
- (7) Moderate exercise of 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 research investigator does not manipulate subjects= behavior and the research will not involve stress to the subjects.
- (10) Research on drugs and devices for which an investigational new drug exemption or an investigational device exemption is not required.
- (11) Any other category specifically added to this list by HHS and published in the Federal Register.

* Subjects must be informed orally of the risk of bruising and infection.

** Moderate exercise does not include stress testing.

7.2.2 Informed consent is required, but the requirement to obtain a signed consent form may be waived if:

- (1) 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) 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.

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

7.3 Full Review

All those projects not exempt or qualifying for expedited review shall be subject to full review by the IRB.

8. REVIEW PROCEDURES

8.1 Exempt Review

Under the exempt procedure, the researcher shall submit Form A to the Chair of the IRB. The IRB Chair shall determine whether a project is exempt from further review. Although exempt research requires no action by the IRB, the board may choose to review the forms on file at its discretion. If the Board deems necessary, it may require a full review.

8.2 Expedited review

- 8.2.1 Research which involves no more than minimal risk to the subject and falls under the categories established by the Secretary of Health and Human Services (46 FR 8392), or research previously approved needing minor changes, will normally be reviewed by the expedited review procedures. However, the IRB may consider any such research through a full review procedure, if it so chooses.
- 8.2.2 Informed consent is required in the expedited review, but the IRB may waive the requirement to obtain a signed consent form, in accordance with the guidelines discussed above in section 7.2.2.
- 8.2.3 In cases where the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.
- 8.2.4 Under the expedited review procedure, the researcher shall submit Form B to the IRB Chair. The Chair will appoint a committee member to review the proposal. A member of the IRB shall not review his/her own proposal. If the reviewer finds that the research falls under the guidelines for expedited procedures, the reviewer has the authority to approve the project, require modifications in the project, or recommend a full review by the IRB. The reviewer will report his/her action at the next IRB meeting. A research activity may be disapproved only after a review by the full IRB. The reviewer shall forward to the IRB Secretary the research proposal and his/her decision to

approve the proposed research activity, or his/her modifications required to secure the reviewer's approval, or a recommendation for full IRB review. The IRB Secretary will make the proposal and decisions available to all members of the IRB.

8.3 Full Review

- 8.3.1 Investigators are required to submit proposals to the IRB Chair on Form B at least 10 days in advance of the meeting in order to provide time for prior review. The committee may approve the research as proposed; it may approve the research pending specified modifications; or it may reject the research proposal. If the IRB gives approval pending specified modifications, the principal investigator is required to submit written assurance that conditions, restrictions, report requirements, or changes imposed on the project will be followed.
- 8.3.2 The ultimate protection of safety, confidentiality, and the rights of human subjects will in all cases take precedence over the importance and results of the project. The definition used to determine if the subject is "at risk" will be contained in the Code of Federal Regulations on Protection of Human Subjects (45 CFR 46 as amended).
- 8.3.3 No project or activity which involves humans will be approved unless assurances of legally effective informed consent are provided for or a waiver of signed informed consent is approved on Form B by the IRB. The elements of informed consent as outlined by article 46.116 of 45 CFR 46 are to be observed in all projects. The Board will decide whether the method for securing consent of the subject (by the principal Investigator) is sufficient and appropriate. Additionally, in connection with any project involving fetuses or pregnant women, the IRB will oversee the actual process by which individual consents are secured by sampling and monitoring the progress of the activity at timely intervals.

9. RECORDS

- 9.1 The IRB Secretary will obtain and maintain all appropriate records—including, but not limited to, copies of all projects, documentation of informed consent procedures, minutes, and records of formal notification to/from principal investigators of official actions—in the Office of Sponsored Programs. All such records will be reviewed for informational content and follow up by the Chair of the IRB.
- 9.2 All records obtained for compliance with 45 CFR 46 are considered privileged institutional records and principal investigators must protect and maintain the confidentiality of information on individual subjects. Certification of approval of federally funded projects including any required changes will be forwarded by the IRB Chair to the Department of Health and Human Services.

10. STATEMENT ON STUDENT RESEARCH

- 10.1 According to federal regulations, research is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.” If student projects are not designed to contribute to further academic knowledge in the discipline (e.g., conference presentations, professional publications), then they are not considered research for the purposes of this rule and therefore are not under the review of the IRB. Student projects that are designed to contribute to generalized knowledge should be submitted for review to the IRB just as any other research project.
- 10.2 Research conducted by students must follow the same ethical guidelines as all university research. The responsibility for the ethical conduct of student research is jointly held by the instructor and the student, each being fully responsible for the research.

Contact for Interpretation: Chair, Institutional Review Board