

Policies and Procedures for Personnel Engaged  
in Research Involving Human Subjects



Texas A&M University-San Antonio  
One University Way  
San Antonio, Texas 78224

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## PREFACE

This document is provided for all Texas A&M University-San Antonio (TAMU-SA) faculty, staff, and students who conduct or who plan to conduct research with human subjects. All human subjects involved in such projects, regardless of their affiliation with TAMU-SA (and regardless of where the research activities are actually conducted) shall be protected by policies and procedures documented in this document.

A key requirement regarding the protection of human subjects is that all persons who plan to conduct research (a study) involving human subjects must first submit a proposal to the University institutional Review Board for the Protection of Human subjects (IRB). Please refer to the University website for details. Researchers **may not begin** any research with human subjects until the proposal has been officially **approved** by the IRB. Policies and procedures contained in this document comply with requirements documented in the Code of Federal Regulations (45 CFC 46) concerning conducting research with human subjects.

The importance of obtaining official **IRB approval** of proposed research projects cannot be overemphasized. Conducting research with human subjects without IRB approval is a violation of Federal Regulations. Consequences of violations can be very serious for the individual researcher and the University. Possible penalties include loss of the University's ability to obtain federal funds including monies for student federal aid. University sanctions may be imposed on researchers found to have violated Federal Regulations or University policies and procedures.

In order to ensure that information contained this manual is as current as possible, the Board will incorporate any changes in regulations applicable to the University either through the use of appendices to the manual or by revision of the manual itself.

Researchers who have questions about conducting research with human subjects should contact the Chair, the members of the IRB who represents their college/department, or any member of the IRB. Please refer to the University Website for contact information.

Dr. Josephine Sosa-Fey  
Director of Graduate Studies & Research  
Chair of the Institutional Review Board (IRB)

## I. DEFINITION OF TERMS

1. **Research** means systematic investigation designed to develop or contribute to generalizable knowledge. Under this definition some demonstration, service, and training projects may be considered to include research activities.
2. **Human Subject** means a living individual about whom an investigator conducting research obtains: a) data through intervention or interaction with the individual, or b) identifiable, private information.
3. **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 that individual can reasonably expect will not be made public i.e. a medical record.
4. **Minimal Risk** means that the risks of harm anticipated in the proposed research are not greater in either probability or magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.
5. **Informed Consent** means the knowing, legally effective consent of any individual or the individual's legally authorized representative. Such consent can be obtained only after subjects are given sufficient opportunity to consider whether or not to participate. Furthermore, informed consent can be obtained only under conditions that minimize the possibility of coercion or undue influence.
6. **Legally Authorized Representative** means an individual or judicial or other body authorized under applicable law to give consent on behalf of a prospective subject to the subject's participation in the research procedure(s).

## II. STATEMENT OF PRINCIPLES

Texas A&M University-San Antonio is committed to the pursuit of excellence in teaching, research and public service. At the same time, the University seeks to protect the welfare of every person who may be involved in research and training projects. Members of the University community, while upholding the highest standards of freedom of inquiry and communication, accept the responsibility this freedom offers; for competence, for objectivity, for consideration of the best interests of the University and society, and for the welfare of every participant in a project. The University gives assurance that it will comply with the Department of Health and Human Services (DHHS) regulations for the Protection of Human Subjects (45 CFR 46, as amended).

1. All activities involving humans as subjects must provide for the safety, health, and welfare of every individual. Rights, including the right of privacy, must not be infringed.
2. Since the participation of humans in research and/or training projects may raise fundamental ethical and civil rights questions, no distinctions in the monitoring of projects will be drawn between funded and unfunded projects, sponsored and unsponsored projects, or between projects carried out by students, faculty, or other University employees, on-campus or off-campus.
3. The direct or potential benefits to the subjects, or the importance of the knowledge to be gained, must outweigh the inherent risks to the individual.
4. Participation in projects must be voluntary and, except as provided in Section C of this document, informed consent must be obtained from all subjects. Consent should be obtained whenever possible from the participants themselves. If a subject is not legally or physically capable

of giving informed consent, a legally authorized representative may do so. Careful consideration shall be given to the representative's depth of interest and concern with the subject's rights and welfare. Parents for example, may not expose their child to risk except for the child's benefit.

5. It is the primary responsibility of the investigator to safeguard information in the course of an investigation. Such information shall not be communicated to others unless the following conditions are met: Explicit permission for the release of identifying data is given by the individual. When data are released with permission, the investigator assumes responsibility for adequately disguising individual sources. Information about individuals may be discussed only for professional purposes and only with persons clearly concerned with the project. Written and oral reports should present only data germane to the purpose of the project, and every effort should be made to avoid invasion of privacy.
6. Projects will be continually reviewed by the Institutional Review Board (IRB) using the procedures described in (Section IV). All members of the university community involved in investigation and training are responsible for continual monitoring to assure compliance of their research with these principals.
7. No individual involved in the conduct and/or supervision of a specific project shall participate in the IRB review, except to provide information.
8. A second review may be required if a long interval has elapsed between an IRB review and project initiation, the proposed effort

is in a rapidly changing scientific area, or the principal investigator wishes to change procedures after the proposed project has been approved by the IRB. **In no case will work take place without at least an annual review by the Chair of the IRB or his or her designee.**

9. In all cases, the investigator should show practical regard for the Texas A&M University-San Antonio community, recognizing that violations of the ethical and legal standards incorporated in this statement of principles (for example, concerning confidentiality, informed consent, debriefing, and regard for the health, safety, and welfare of all human subjects) could impugn the investigator's own name and the reputation of the University.

The investigator does not abdicate ethical and legal responsibility merely by complying with this protocol. It is always the responsibility of the investigator to obtain clearance from the IRB prior to the initiation of any non-exempt research activity involving the use of human subjects. **Failure to do so may result in personal restrictions on the research activities of such individuals, as well as potentially endangering all federal funding to the University.**

### **III. INSTITUTIONAL REVIEW BOARD MEMBERSHIP & INSTITUTIONAL RESONSIBILITIES**

The Institutional Review Board for the Protection of Human Subjects (IRB) shall be composed of representatives from the faculty, student, and lay communities. The Board may, at its discretion, invite individuals with competence in special areas to assist in the review of particular applications/proposals which require expertise beyond or in addition to that available on the Board. These individuals shall have no voting rights.

All non-exempt research projects involving the use of human subjects must be submitted to the IRB for approval. Except as provided in 3, below, and Section VI of this document, applications shall be submitted to the Office of Graduate Studies & Research well in advance of the deadline for which the proposal is to be submitted if being submitted to an external funding agency or on which the research is to begin. Sample applications/proposals for approval of investigations involving the use of human subjects are provided on the University website.

The Institutional Review Board for the Protection of Human Subjects will meet as a full-board monthly during the academic year to review research proposals that involve: 1) research with minors, 2) pregnant women, 3) prisoners, and 4) human subjects who will encounter more than minimal risk in the research. A copy of the Board Meeting schedule may be obtained upon request from the Office of Graduate Studies & Research.

To assure consideration of an Expedited Review application by the IRB in any given semester, the Principal Investigator must initially submit two copies (original, plus 1 copy) of a completed application to the Office of Graduate Studies & Research no later than fifteen days prior to the next



scheduled meeting. This will allow sufficient time for the screening process prior to the scheduled IRB meeting.

An Expedited Review procedure is established for those applications which involve no more than minimal risk to subjects and which also fall under one of the research categories eligible for expedited review (see Section VI for a complete list of expedited research categories).

Determination as to whether a specific project is eligible for expedited review will be made by the Chair of the IRB, who may designate one or more members of the IRB to conduct the expedited review in accordance with Section VI of this document. Such designation may cover categories of projects. For example, student projects of a class or department may be assigned to an IRB member with expertise in the area of proposed research activity. The College Dean, Departmental Chair or Director is responsible for ensuring that research by individuals (faculty, students, or employees) is conducted according to human subjects' guidelines.

The IRB shall first determine whether the human subjects are "at risk" (in that they might be exposed to the possibility of harm—physical, psychological, sociological, etc.) as a consequence of their role in the project. If risk does exist, the IRB will proceed to weigh the following primary factors:

- a. That the rights and welfare of the subjects at risk will be adequately protected. Each project will be scrutinized with the interest of the subjects foremost in mind. No procedure shall be followed that would result in unnecessary or unacceptable risks to the subjects. Appropriate safeguards and emergency measures must be provided. The IRBs concerned with the

maintenance of proper records and the protection of anonymity and confidentiality of all data collected. Furthermore, the IRB will attempt to minimize personal embarrassment, mental anguish, and questions of conscience resulting from participating in a study. In short, the IRB shall make every effort to ascertain that both the mental and physical well-being of the subjects are adequately protected.

- b. That the risks to the subject are outweighed by the benefits. The project will be evaluated to determine if the potential for hazard to subjects is outweighed by possible benefits to them or by the importance of the knowledge to be gained. The IRB expects that human subjects will not be utilized in projects which are poorly designed. However, the responsibility for **monitoring research design** quality lies primarily with the appropriate college dean or departmental head or faculty sponsor.
- c. That the informed consent of subjects will be obtained by adequate and appropriate methods (described in Section V). All subjects will be fully informed by the investigator, of the procedures to be followed, including discomforts, risks, and possible benefits. Risks must be well defined in terms understandable to the subjects. Informed consent must be obtained in writing from all subjects in this category, unless doing so will jeopardize the goals of the research project.

A majority of the members of the IRB must be present at a meeting in order to conduct official business. Final approval by the IRB shall then require a majority vote by members present. If the

IRB agrees that the proposed research protects human subjects in accordance with established standards, its conclusion shall constitute certification of approval. A letter expressing the outcome of the review will be sent to the investigator.

In the case of a proposal being submitted to an external funding agency, certification of approval of the protocol, if required, will be made at the time the proposal is submitted in the form required by the agency. In order to do this, a copy of the proposal must be forwarded with sufficient time to the IRB prior to its submission to an external sponsor.

#### **IV. REVIEW PROCEDURES AND CRITERIA FOR APPROVAL**

1. The Principal Investigator may be asked to meet with the IRB should it be apparent that clarification or modification of statements in the application are required. In addition, the IRB may elect to impose other restrictions or recommendations under which the project shall be conducted. No individual involved in the conduct and/or supervision of the research project shall participate in its review, except to provide information to the IRB.
2. If the IRB action is to disapprove the application, reasons for this negative decision will be provided in writing to the Principal Investigator or Project Director. If the researcher decides to modify the proposed research in such a way as to meet the objections of the IRB, the investigator may resubmit the application for consideration at the next IRB meeting. If desired, the investigator may request a personal hearing at the next scheduled IRB meeting.
3. Any substantial changes in the protocol, emergence of problems or development of hazardous conditions for the subject, must be reported immediately to the IRB by the responsible investigator. An amended protocol must then be approved by the IRB or its designee before the research may continue.
4. When initial approval of a protocol is given, the IRB will indicate the minimum intervals of time between re-evaluation of the project so that continued acceptance of the protocol is assured. Routine projects may be reviewed at yearly intervals; more complex and potentially dangerous projects will be reviewed at a frequency commensurate with the related risks.

Projects that are determined to be exempt will not require additional review. Renewal projects should include a progress report as well as a description of any anticipated design changes. Projects may also be re-evaluated if subjects involved in the research lodge a complaint with the IRB, or the Principal Investigator reports problems with the research. In the latter case, the IRB may elect to review both the Investigational staff and persons under risk.

5. Certain proposals may be submitted with the knowledge that human subjects are to be involved with the project, even though definite plans for this involvement remain inconclusive. Such proposals shall be reviewed and certified in the same manner as more complete applications with the obligation that later review and approval will be required as more complete plans are made, but before the period during which human subjects would be utilized. In the case of an externally funded project, this later review and approval must precede the beginning of any grant budget period which human subjects would be utilized.
6. Ongoing projects modified to include humans as subjects must also be submitted to the IRB for review and approval prior to the use of human subjects. In the case of an externally funded project, the granting agency would be notified of the IRB action prior to the appropriation cycle for a budget period during which human subject involvement is proposed.

## **V. INFORMED CONSENT**

Informed consent is a process, not just a piece of paper. A written informed consent documents this process, but cannot serve as a substitute for it. Except as provided below, no subject may be involved in a non-exempt research activity without the legally effective informed consent of the subject or the subject's legally authorized representative. This consent shall be sought under circumstances that provide sufficient opportunities for the subject to freely consider whether or not to participate. Particular attention should be given to minimizing the possibility of coercion or undue influence.

The information given to the subject or the subject's legally authorized representative must be in simple, easily understood language. If the subject population is not English speaking, the informed consent must be presented in whatever language is appropriate.

In general, a written informed consent which requires the signature of the subject or subject's representative is required only when the proposed procedures pose more than minimal risk to the subject. If the subject is a minor, written parental consent is required unless this requirement is specifically waived by the IRB. A waiver of the written informed consent requirement will be granted by the IRB or its appointed screening committee only if the investigator can provide adequate justification for the request.

There exist situations where informed consent may be waived: 1) Research that involves no more than minimal risk; 2) The rights and welfare of the subjects are not adversely affected; 3) The research could not be practically conducted without a waiver, 4) The subject is to be provided information after participation, if applicable. If the proposed procedure poses no more than minimal risk to the subject, informed consent may be obtained via a cover letter or orally.

Further, if the only record linking the subject to the research or data is the written, signed informed consent, its use may be waived by the IRB or its appointed screening committee. However, a statement describing the procedures and objectives of the research shall still be supplied to the subjects in either a written or oral format.

In instances of minimal risk research for which written consent is not required, it may nevertheless be desirable to enhance the communication of professionalism of the undertaking by providing a written consent agreement containing appropriate elements of information. Furthermore, investigators whose projects are exempt from IRB review may, if they wish, submit such projects for review. The IRB approval statement thereby acquired might also be seen as a means of enhancing subjects' trust and willingness to participate. An example of such a project would be the analysis of a questionnaire which is distributed and returned anonymously through the mail.

If informed consent is to be obtained by use of the prescribed or modified document, copies of the proposed form will be included in the application to the IRB. If informed consent is to be obtained orally, a written summary of what subjects will be told and at what point in the research process, will be provided to the IRB for review.

This provision recognizes that some areas of research require procedures in which subjects must remain temporarily "blind" to factors of experimental interest. In these instances, certain elements of information and final agreements to continued participation might occur after some information or observations have been obtained.

No informed consent, whether oral or written, may waive or limit in appearance or in fact, the subject's legal rights, including any release of the institution or its agents from liability or negligence.

The following information shall be supplied in all required written informed consent documents:

1. An explanation of the scope, aims and purposes of the research, and the procedures to be followed, including the expected duration of the subject's participation. This statement should include a description of any anticipated benefits the subject or others might reasonably expect.
2. Identification of the responsible investigator, as well as the name of any sponsoring or funding source supporting the research. Texas A&M University-San Antonio shall be identified as the, or one of the, responsible institution(s).
3. The following statement will be included in ALL written informed consents (including cover letters). The statement must be inserted at the bottom margin of the form or letter.  

THIS PROJECT HAS BEEN REVIEWED BY THE TEXAS A&M  
UNIVERSITY-SAN ANTONIO INSTITUTIONAL REVIEW BOARD FOR  
THE PROTECTION OF HUMAN SUBJECTS,
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A description of any reasonably foreseeable risks or discomforts to the subject (including likely results if an experimental treatment should prove ineffective). If the risk potential is currently unknown or unmeasurable, a statement to that effect will be required.
6. A statement regarding the availability of compensation and/or medical treatment, if injury occurs, will be required for research which involves more than minimal risk. If compensation or medical treatment will be provided, information about how it may be obtained or where further information may be secured will be required.



7. A statement that any new information developed during the course of the research which may influence the subject's willingness to continue participation will be provided. Related to this, an offer to answer any questions the subject (or subject's representative) might have regarding the subject's rights shall be included. This statement should include the name, address, and/or telephone number of the principal investigator.
8. A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
9. A statement that participation is voluntary and that refusal to participate or a subsequent decision to discontinue participation will not result in penalty or loss of benefits to which the subject is otherwise entitled. This statement should include a description of the consequences, if any, that would accompany such a decision to withdraw.
10. A copy of the informed consent shall be supplied to the subject or the subject's legally authorized representative.
11. Federal law mandates that copies of all required informed consent documents be retained for a minimum of five years. The Office of Graduate Studies & Research will provide maintenance and retention of such records. Signed consent forms must be kept for 3 years after completion of the project in a locked file cabinet, the location of which is known by the IRB.

## VI. EXPEDITED REVIEW

The DHHS regulations recognize that there are certain categories of research which involve procedures which pose no more than minimal risks to subjects and for which clear standards can be set. Accordingly, research projects which fall under one of the categories listed below will be eligible for an expedited review.

Under the expedited review procedure, the review will be carried out by the IRB Chair or by one or more experienced reviewers designated by the Chair 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 the non-expedited procedure set forth in Section IV of this document.

The IRB Chair and IRB reviewers appointed by the Chair under these provisions will report annually to the full IRB all research proposals which have been approved under this procedure, those referred to the IRB by the reviewers, and those withdrawn by the proposer after failure of expedited approval (such an action might be occasioned by time constraints).

Listed below are several examples of categories subject to expedited review. Expedited review will be given for research protocols which involve no more than minimal risk to the subjects and in which the only involvement of human subjects falls under one of the following examples:

1. Minor modifications or additions to existing approved studies
2. 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

3. The study of existing data, documents, records, pathological specimens or diagnostic specimens that include information that could be used to identify individual subjects
4. Voice recording made for research purposes such as investigations of speech defects;
5. Moderate exercise by healthy volunteers
6. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice
7. Collection of blood samples by venipuncture, in amounts not exceeding 45 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
8. Collection for analysis of excreta and external secretions from subjects 18 years of age or older.

## VII. EXEMPTIONS

The University has identified seven categories of research which are exempt from IRB review based upon DHHS regulations (45 CFR 46, paragraph 46.101-b). Research activities, in which the only involvement of human subjects will be in one or more of these categories are exempt from IRB review.

However, it should be emphasized that, even if a research activity with human subjects is exempt from IRB review and approval, the general requirements for informed consent where appropriate for ethical treatment of subjects and for protection of participants still apply. The following categories of exemption have been adopted by Texas A&M University- San Antonio:

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), if information taken from these sources is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
3. Research involving survey or interviewing procedures, EXCEPT where all of the following conditions exist
  - a. Responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers link to the subject
  - b. The subject's responses, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and

- c. The research deals with sensitive aspects of the subject's behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
4. Research involving the observation (including observation by participants) of public behavior, EXCEPT where all of the following conditions exist:
  - a. Observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subject,
  - b. The observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability, and except for research involving children
  - c. The research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.
5. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publically 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.
6. Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine:
  - public benefit or service programs;
  - procedures for obtaining benefits or services under these program;
  - possible changes in or alternatives to those programs or procedures; or –
  - possible changes in methods or levels of payment for benefits or services under those programs.

## Appendix A

### Links to Important Documents and Websites

[The Belmont Report](#)

Code of Federal Regulations-Protection of Human Subjects [45 CFR 46](#)

US Department of Health & Human Services-

[Human Subjects Regulations Decision Chart](#)

[Informed Consent Checklist](#)

Link to Required CITI Training on using HUMAN SUBJECTS in Research.

<https://www.citiprogram.org/default.asp?language=english>

This document was adapted (with the permission of Dr. Ambrose O. Anoruo, Dean of the College of Graduate Studies), from the 2008 Texas A&M University-Kingsville Manual for Personnel Engaged in Research Involving Human Subjects.