

Texas A&M University-Commerce
IRB Procedure and Guidelines Manual for Research with
Human Subjects

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Introduction

This manual is intended to provide information and guidance to faculty, students, and staff of Texas A&M University-Commerce that are engaged in research with human subjects. In addition, it is intended to begin the needed process of bringing the University into compliance with existing Federal law and regulations regarding the protection of human subjects in research. This manual does not address ethical and procedural concerns related to the use of animals in research; persons contemplating conducting research with animals should refer to the National Institute of Health or the Association For Assessment and Accreditation of Laboratory Animal Care International for information. Much of the information in this manual is copied directly from Federal regulations or, with the kind permission of Dr. Barbara Sterry, from the Policy and Procedure Manual for Research with Human Subjects of Nova Southeastern University.

The National Research Act Public Law 99-158, the most recent extension of The Health Research Extension Act of 1985, and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, provide guidelines for research with human subjects to ensure their protection in the design and conduct of research. These federal regulations require that any institution requesting and receiving funds from a federal department or agency for research involving human subjects must assure that such research is reviewed and approved by the institution's Institutional Review Board (IRB). These laws were implemented by regulation in the Code Of Federal Regulations, Title 45 Public Welfare, Department Of Health And Human Services, National Institutes Of Health, Office For Protection From Research Risks, Part 46, Protection Of Human Subjects, Revised June 18, 1991, Effective August 19, 1991.

Any research that involves human subjects conducted by TAMU-Commerce faculty, staff or students, whether funded or unfunded, is required to be under the jurisdiction of the IRB. The IRB is responsible for determining and assuring that 1) the welfare and rights of human subjects are adequately protected and informed consent given, if necessary; 2) human subjects are not placed at unreasonable physical, mental, or emotional risk as a result of research; 3) the necessity and importance of the research outweighs the risks to the subjects; and 4) the researcher(s) is/are qualified to conduct research involving human subjects. Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB (§46.112 of the Federal Policy for the Protection of Human Subjects).

Members of the IRB Committee will be appointed by the President of the University to staggered three-year terms. The Chair will be granted one course release time per semester, including summers, from his/her assigned teaching responsibilities for the period of the appointment. Additionally, the Chair, and/or other members of the IRB, will be responsible for training faculty, students, staff and new appointees to the IRB regarding the procedures and requirement for the protection of human subjects in

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research. Requirement for membership of the IRB is described in §46.107 of the Federal Policy for the Protection of Human Subjects as follows:

- (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 a conflicting interest, except to provide information requested by the IRB.
- (f) An IRB may, in 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

For all funded research involving human subjects, the Graduate School will be responsible for coordinating the submission of required documentation to the IRB for review. In the case of unfunded research involving human subjects, faculty, staff, and students proposing research involving human subjects will submit all documentation,

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including the DHSPC/IRB submission form and IRB protocol form, to the designated Departmental Human Subjects Protection Committee (DHSPC), which will be responsible for the initial review of the research. All research proposals must be initially and thoroughly reviewed by the each DHSPC. For University staff that are not associated with an academic department, such as the library and Zeppa Center, research proposals should be submitted directly to the IRB. After Departmental review, the appropriate documentation of this review, including the DHSPC/IRB submission form and IRB protocol form, must be presented by the researcher to the IRB. All documentation associated with DHSPC and IRB reviews will be maintained within the Graduate School. The Graduate School will provide staff support to the IRB in all phases of its work, track and monitor submissions, and maintain records related to all research involving human subjects.

All research proposals must be approved by the DHSPC, IRB, and Graduate School prior to the researcher(s) having any contact with potential subjects. It is highly recommended that graduate students completing a thesis or dissertation obtain approval from the IRB prior to the presentation of their proposal.

All proposals submitted to the IRB will be reviewed in a timely manner, typically within one week after receipt during the fall and spring semesters for proposals that are submitted electronically and subject to expedited review. Proposals requiring full review will be scheduled for review at the next monthly meeting of the IRB. To facilitate prompt review, all submissions to the IRB must be electronically submitted, i.e., submitted via email, file attachments, or fax.

Summary of Proposed Changes

The current University IRB procedure (A15.02) is not in compliance with the National Research Act Public Law 99-158 or the Code Of Federal Regulations, Title 45 Public Welfare, Department Of Health And Human Services, National Institutes Of Health, Office For Protection From Research Risks, Part 46, Protection Of Human Subjects, Revised June 18, 1991. The proposed IRB procedure and guidelines contained in this document are intended to be more consistent with the Federal requirements. The essential elements of this proposal, with many details omitted for brevity, are:

- The IRB Committee membership will be reconstituted to be in compliance with Federal requirements. The IRB Chairperson would be released one course per semester, including summers.
- All Departments will form functioning Departmental Human Subjects Protection Committees (DHSPC) and such Departmental Committees shall review all protocols submitted by faculty, students, and staff of the respective Department.
- After protocols are reviewed and approved by the DHSPC, a notice of the completed review will be forwarded to the IRB and the researcher will be notified that the protocol should be submitted to the IRB for approval.
- The IRB will review all protocols for all research conducted by all faculty members, students, and staff, as required by Federal rules. Minimum risk

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protocols will be reviewed via expedited review, typically within one week of submission, if submitted electronically. Protocols that may be exempt from IRB review can only be identified as exempt after submission to the IRB. For all proposed research, IRB approval would be required prior to any contact with human subjects. Notification of IRB approval will be provided to the applicant, the DHSPC, the faculty advisor in the case of dissertations and theses, and the Graduate School

- The Graduate School Dean will be the authorized IRB institutional official for representing the University. The Graduate School would provide documentation and record keeping support and other forms of assistance for the functioning of the IRB. The IRB and the Graduate School would be responsible for disseminating both training and IRB related materials and resources to faculty, students, and staff.

Definitions

(from §46.102 of the Federal Policy for the Protection of Human Subjects)

- (a) *Department or Agency head* means the head of any Federal Department or Agency and 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 generalizable 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).

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(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 policy.

(h) *IRB approval* means the determination of the IRB that the research has been reviewed and may be conducted at an institution 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 the institution to the supporting Department or Agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance.

Departmental Human Subjects Protection Committees

All departments within the University shall constitute a Departmental Human Subjects Protection Committee (DHSPC). This committee shall be composed of a minimum of three faculty members who are familiar with the conduct of research in their discipline. Additional members, including student members, are permissible. The DHSPC shall review all proposals submitted by faculty members, students, and staff members within that department. The review process must involve joint review and communication among all members of the DHSPC. Applicants should submit to the DHSPC the IRB submission form and IRB protocol form. This will simplify the process for applicants and help insure that the research protocol is consistent with IRB requirements.

Research Covered by and Exempt from IRB Review

To comply with the federal guidelines covering the protection of research subjects, and to ensure appropriate ethical management of research programs conducted by TAMU-Commerce faculty, staff, and students, all **funded and unfunded** research proposals involving any risk to human subjects falls within the jurisdiction of the IRB. The DHSPC can recommend that the research should be considered minimal risk by the IRB, however only the IRB can decide if the research is indeed minimal risk or if the protocol falls into one of the "exempt" categories. Exempt status implies that full review by the IRB is not necessary; it does not imply that initial review by the IRB is not required.

Research Requiring Full IRB Review

Research which has potential risk to subjects includes, but is not limited to, the following:

- Research which involves the administration of drugs or other substances to subjects
- Research involving pregnant women and/or fetuses in utero
- Research involving subjects with life-threatening physical conditions
- Research involving physically intrusive procedures
- Research which previous experience (by the particular investigator or other investigators) has shown to create a potential of risk to subjects
- Research which potentially could put the subject at risk for legal or civil liability or invade a subject's privacy in regard to sensitive aspects of his/her behavior (e.g., illegal conduct, drug use, sexual behavior, alcohol use).

Research Exempted From Full IRB Review

All research proposals must be reviewed by the appropriate DHSPC prior to review by the IRB. Exempted categories of research from full IRB review, under §46.101 of the Federal Policy for the Protection of Human Subjects, include:

(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 subjects' responses outside the research

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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 (b)(2) 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, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

(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.

Types of Review

Full Review

A full review of proposed research shall take place at convened meetings when at least one-half of the IRB members are present, including the non-scientist member. In order to approve research, the IRB shall determine that all criteria for approval are satisfied. These criteria, from §46.111 of the Federal Policy for the Protection of Human Subjects, are listed below:

- (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 anticipated benefits, if any, to subjects, and 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 disable persons, or economically or educationally disadvantaged persons.
- (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
- (5) Informed consent will be appropriately documented.
- (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- (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.

DHSPC reviews should address these same criteria when reviewing research proposals.

Expedited Review

Expedited review allows the TAMU-Commerce IRB to use an abbreviated review procedure for research proposals involving human subjects. To qualify for expedited review, two criteria must be met.

1. The research must involve no more than minimal risk to the human subjects, **and**
2. The research must consist entirely of one or more of the following specific activities:
 - Collection of hair and nail clippings in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction
 - Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor
 - 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 input of matter or significant amounts of energy into the subject or invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves)
 - 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 and who are in good health and not pregnant
 - 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
 - Voice recordings made for research purposes, such as investigations of speech defects
 - Moderate exercise by healthy volunteers
 - The study of existing data, documents, records, pathological specimens, or diagnostic specimens
 - Research on individual or group behavior characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the

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investigator does not manipulate subjects; behavior and the research will not involve stress to subjects

- Research on drugs or devices for which an investigational device exemption is not required.

For example: An audio tape on which subjects are asked to speak common words for the purpose of measuring voice timber would qualify for expedited review. A tape of a therapy session with a patient would not qualify for expedited review. Although the research involved an audiotape, the sensitive nature of the contents would require a full review.

Additionally, expedited review may be used when there are minor changes in previously approved research during the period (one year or less) for which approval is authorized.

The IRB will have responsibility for determining which protocols do or do not meet the criteria for expedited review. Expedited review may be carried out by the IRB Chair or by one or more IRB members designated by the Chair. When conducting an expedited review, IRB members may exercise all of the authorities of the IRB, except that the reviewer(s) may not disapprove the research. A research activity may be disapproved only after a full IRB review has been conducted.

Proposals that may be considered "exempt" from full IRB review and minimal risk will typically be reviewed under expedited review. All IRB members will be informed regarding the status of research proposals that have been approved using expedited procedures prior to or at the next regularly scheduled IRB meeting.

Review Continuation/Renewal

Continuing review of research must be conducted at intervals appropriate to the degree of risk, but not less than once per year. The IRB cannot approve a research project for more than 12 months. All reviews for continuation will be conducted by expedited review, if no changes have been made to the research protocol and no adverse or unexpected reactions or side effects have occurred or are expected. (However, the full IRB will be given the opportunity to review the continuation/renewal report.) In all other instances, continuing review will be conducted by the full IRB.

If the investigator, during the course of conducting the research, revises the research protocol (e.g., makes changes to the informed consent form, survey instruments used, or number and nature of subjects), the principal investigator must notify the IRB Chair immediately, and in the case of funded research, the Office of Grants and Contracts. The Chair will determine the need for additional review, the type of review full or expedited and notify the IRB members.

Types of IRB Actions

The IRB shall review and have the authority to approve, tentatively approve pending receipt of additional information, or disapprove the subject research according to the following.

Approve

The protocol is approved as submitted.

Pending

A protocol is considered pending when the problems identified in the protocol are not serious and generally fall into two categories: 1) the investigator needs to clarify an aspect of the study or provide additional information, or 2) minor changes need to be made in the informed consent document. In these cases, approval can be given after the investigator rewrites the informed consent and/or submits to the Chair a written response to the IRB's questions and concerns. The Chair will then poll IRB members to receive final approval.

Disapprove

The IRB will disapprove the proposed research if it places the subjects at risks, which far outweigh the benefit or value of the knowledge to be gained, or it raises such serious ethical questions as to be unacceptable. In the event a disapproval is foreseen, the investigator may be invited to attend the meeting of the IRB to discuss the protocol. A research activity may be disapproved only after a full IRB review has been conducted.

In each of the above cases, the IRB shall notify the principal investigator of the results of its action in writing

Certifications

Certification of IRB Review (for Funded Projects only)

Certification of IRB review refers to the official notification by the university to the appropriate regulatory/governmental agencies that the research activity or project involving human subjects has been reviewed by the IRB. Institutions that engage in research funded by the Department of Health and Human Services (DHHS) must file an assurance of compliance with the agency's regulations governing the protection of human subjects. The assurance is a written agreement, which includes the following:

- A statement of ethical principles and institutional policies governing research involving human subjects
- IRB, institution, and investigator compliance with 45 CFR Part 46
- Certification of IRB approval and institutional endorsement

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- A list of IRB members and their qualifications

Institutions of higher education normally use one of two mechanisms for providing assurance of compliance. These include:

- *Single Project Assurance (SPA)* An SPA acknowledges intent to comply with DHHS human subjects regulations in the conduct of a **specific** research project or activity. At the time of submission of the grant proposal, the University indicates, usually on the face page of the proposal, a willingness to comply with DHHS regulations. Once the decision is made to fund the proposal, the appropriate funding agency contacts the OPRR, which in turn contacts the University. The University submits additional documentation and the SPA. The OPRR reviews the assurance and, if approved, assigns an assurance number to the project or activity. The SPA is generally used by institutions whose level of DHHS-supported research involving human subjects is low. NSU routinely uses the SPA.
- *Multiple Project Assurance (MPA)* Institutions of higher education that engage in a significant number of DHHS-sponsored research projects or activities involving human subjects are invited to file a MPA. The OPRR receives the assurance, negotiates the final agreement, and assigns an assurance number to the institution. NSU currently does not have a MPA.

Suspension or Termination of Research

The IRB shall have authority to suspend or terminate research that is not being conducted in accordance with the IRB's requirements, other institutional and federal requirements, or has been associated with any serious harm to subjects. Concerns regarding the conduct of research must be reported immediately to the Chair of the IRB by any individual having such knowledge. Any suspension or termination of research must include a statement of the IRB's action and the Chair must report its decision promptly to the principal investigator, the Office of Grants and Contracts of the Graduate School, and the funding agency, in the case of a sponsored project.

Cooperative Research

Cooperative research projects are those that involve more than one institution and can be designed to be both multi-site and multi-protocol in nature. In the conduct of such projects, each participating institution is responsible for safeguarding the rights and welfare of human subjects and for complying with all regulations.

- **Institutional Approval:** In cases where the research project will be housed and conducted at another institution with participation by TAMU-Commerce faculty, staff, or research participants, it is required that documentation of the primary institution's IRB approval and a copy of the research protocol and consent forms be obtained and made part of the TAMU-Commerce records. The proposed research project must then go through an additional review by and receive approval from TAMU-Commerce IRB. All cooperative research projects

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involving TAMU-Commerce faculty, staff, students conducting research as part of their degree program, or research participants, whether conducted at TAMU-Commerce, must have TAMU-Commerce IRB approval.

- **Assurances:** It is the responsibility of the lead institution to file the required assurances and certifications with the Office for Protection from Research Risk (OPRR).

Records

It will be the responsibility of the Chair or the Chair's designee and the Graduate School to prepare and/or maintain adequate documentation of IRB activities regarding research involving human subjects, including the following:

- Copies of all research proposals reviewed and actions taken, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects
- 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 issues of dispute and their resolution
- Records of continuing review of research activities
- Copies of all correspondence between the IRB and investigators
- A list of all IRB members, including their name, race, ethnicity, and gender; earned degrees; affiliation (i.e., Center for Psychological Studies, Health Professions Division-College of Osteopathic Medicine, etc.); indications of experience, such as board certifications, licenses, etc.
- Written procedures governing the IRB.

IRB records must be retained for at least three years; records pertaining to research that is conducted must be retained for three years after completion of the research. All records must be accessible for inspection and copying by authorized representatives of the department or agency supporting or conducting the research at reasonable times and in a reasonable manner [Federal Policy § __.115(b)]. The parent institution of the IRB should provide the IRB with sufficient meeting space and staff to support the IRB's review and record keeping duties [Federal Policy § __.103(b)(2)].

The Authorized Institutional Official.

Within the institution there must be a point of responsibility for the oversight of research and IRB functions. This point should be an official of the institution who has the legal authority to act and speak for the institution, and should be someone who can ensure that the institution will effectively fulfill its research oversight function. The authority can be delegated. The institution's president or chief executive officer (CEO) should appoint or delegate the appointment of the individual. If the CEO does not function as the

Authorized Institutional Official, that person should be the equivalent of the director of research and development, a dean or assistant dean, or hospital administrator. At TAMU-Commerce, this official will be the Dean of the Graduate School.

Training

Training new personnel is a basic responsibility of any institution. In facilities that conduct research, all personnel should be aware of the applicable institutional policies and mechanisms for the approval of research and for reporting problems with research projects in progress. Personnel involved in the conduct of research should receive additional training in institutional expectations and specific regulations pertaining to research. Training designed to enhance the development of high quality proposals should be encouraged. IRB members and others charged with responsibility for reviewing and approving research should receive detailed training in the regulations, guidelines, and policies applicable to human subjects research. Attending workshops and other educational opportunities focused on IRB functions should be encouraged and supported to the extent possible. Training in good research practices and in methods for minimizing risk should be provided.

Informed Consent

One significant outcome of the Nuremberg medical trials was the establishment in 1947 of the Nuremberg Code, which set forth ten principles for conducting research involving human subjects. The first of those principles states, "the voluntary consent of the human subject is absolutely essential." Thus, no investigator may involve a human being as a subject in research, as defined in this manual, unless the investigator has obtained the subject's informed consent. The process of *informed consent* is constituted by two essential elements: (1) the subject has the information he or she requires to make an effective decision, and (2) the subject's participation is not coerced, i.e. his or her consent is voluntary. Once informed consent is obtained, documentation to that effect shall follow the procedures outlined in this manual in the "Documentation" section below.

Additionally, the researcher should be aware that litigation against the University is always a possibility. From this perspective, even an ethical informed consent is not sufficient. Rather, we need an ethical informed consent which is legally valid and the legal validity of which can be demonstrated should such a need arise.

General Requirements

Subsequent to IRB approval, the process of obtaining informed consent shall contain the following elements:

1. It should be obtained from the subject or the subject's legally authorized representative
2. It should be in language understandable to the subject or his or her legal representative

3. It should be obtained under circumstances that provide the subject with the opportunity to consider whether or not to participate, and that minimizes the possibility of coercion or undue influence.

Additional Elements

As needed and considered appropriate by the DHSPC or IRB, one or more of the following elements shall be provided to each subject:

- Statement that procedure may involve unforeseeable risks to the subject
- Description of circumstances under which the subject's participation may be terminated by the investigator without the subject's consent
- Additional costs to the subject resulting from participation in the research
- Consequences of the subject's decision to withdraw from the research and procedures for termination of participation by the subject
- Statement that significant new findings developed during research which may relate to subject's willingness to continue will be provided to the subject
- Approximate number of subjects involved in the study.

Documentation

- Informed consent will be documented by using a written consent form approved by the IRB. The form will be signed by the subject or the subject's authorized representative. A copy will be given to the person signing the form. A written consent documentation should include all of the following basic elements:
 1. a statement that the study involves research
 2. an explanation of the purpose of the research and the expected duration of the subject's participation
 3. a description of the procedures to be followed and the identification of any procedures which are experimental
 4. the disclosure of alternative procedures
 5. a description of risks and possible discomforts to the subject
 6. a description of foreseeable benefits to the subject and others
 7. a description of the extent to which confidentiality will be maintained
 8. an explanation as to whether compensation or medical treatments are available if injury occurs (for research involving more than minimal risk)
 9. an explanation of whom to contact if questions arise or injury occurs
 10. a statement that participation is voluntary, that refusal to participate involves no penalty, and that the subject may discontinue participation and have any data already collected destroyed at any time, and

11. no language through which the subject is made to waive any of his/her legal rights or which releases the investigator, the sponsor, or the institution from liability for negligence.

Exceptions to Documenting Informed Consent

The IRB, upon request, may alter or waive the requirement to obtain a signed consent form for some or all subjects if:

- the only record linking the subject and the research would be the consent document and the principal risk would be harm resulting from breach of confidentiality or
- the research presents no more than minimal risk and involves no procedures for which written consent is normally required.

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

Special Populations

The federal government has extensively regulated and provided additional safeguards with respect to research, development, and related activities involving "special populations"; these include pregnant women and fetuses, prisoners, and children. The following are guidelines for the inclusion of children as subjects in research. For guidelines pertaining to other classes of special populations, please refer to the resources listed at the end of this manual or the IRB Chair, the Chair's designee, or the Graduate School Office of Grants and Contracts.

Children

Research involving children is permitted in the following instances when/if

- the IRB finds that no greater than minimal risk to children is presented, and adequate provisions are made for soliciting the assent of the children and the permission of parents or guardians, as outlined below.
- 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:
 1. the risk is justified by the anticipated benefit to the subjects;
 2. the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

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

1. Wards

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

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

If the IRB approves the research, it shall require the 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 with the research, the investigator(s), or the guardian organization.

2. Requirements for Parental/Guardian Permission and for Assent by Children

The IRB shall require that adequate provisions be made for soliciting the permission of each child's parents or guardians. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient if the research does not involve greater than minimal risk, or does involve greater than minimal risk, but presents the prospect of direct benefit to the individual subjects. If the research involves greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizing knowledge about the subject's disorder or condition, the IRB will require both parents' permission. Exceptions would include: 1) one parent is deceased, unknown, incompetent, or not reasonably available, or 2) when one parent has legal responsibility for the care and custody of the child.

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Permission by parents or guardians shall be documented in accordance with and to the extent required under the Informed Consent section of this manual.

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 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.

Appendice A:

Sources and Information on the Protection of Human Subjects

Prepared by Dean W. Ginther, Ph.D.
(dean_Ginther@tamu-commerce.edu)
Chairperson, TAMU-Commerce University IRB Chairperson
Oct. 2, 2000

WWW Resources Regarding the Protection of Human Subjects

OPRR Human Subject Protections NIH Office of Extramural Research
(<http://ohrp.osophs.dhhs.gov/polasur.htm>)

Code Of Federal Regulations, Title 45, Public Welfare, Department Of Health And Human Services, National Institutes Of Health, Office For Protection From Research Risks, Part 46, Protection Of Human Subjects, Revised June 18, 1991, Effective August 19, 1991

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure
(<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm>)
(<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm#46.110>)

Statutory Basis for Title 45 Code Of Federal Regulations Part 46 Protection Of Human Subjects 45 Cfr 46
(<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/statute.htm>)

Human Subject Regulations Decision Charts
(<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/decisioncharts.htm>)

The Belmont Report, Office of the Secretary, Ethical Principles and Guidelines for the Protection of Human, Subjects of Research, The National Commission for the Protection of Human Subjects, of Biomedical and Behavioral Research, April 18, 1979(<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>)

Human Subject Protections Guidance Documents by Topic
(<http://ohrp.osophs.dhhs.gov/g-topics.htm>)

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Institutional Review Board, (IRB) Guidebook , 1993)
(http://ohrp.osophs.dhhs.gov/irb/irb_guidebook.htm)

Department of Education, Protection of Human Subjects in Research
(<http://ocfo.ed.gov/humansub.htm>)

APA Ethics Office (<http://www.apa.org/ethics/>)

Federal Educational Rights and Privacy Act
(http://www.lrp.com/ed/freelib/free_regs/bc3499.htm)

Nuremberg Code (http://www.irb-irc.com/IRB/ethics_nuremburg.html)

The Declaration of Helsinki (http://www.irb-irc.com/IRB/ethics_helsinki.html)

Guidelines for Writing Consent Forms (http://www.irb-irc.com/IRB/consent_index.html)

Model Consent Form (<http://www.irb-irc.com/IRB/>)

Selected IRB University Homepages:

<http://www.nova.edu/cwis/ogc/irb.html>

<http://www.ofres-hs.upmc.edu/irb/default.html>

<http://www.med.umich.edu/irbmed/>

<http://www.uic.edu/depts/ovcr/oprr/irb/index.html>

Tips On Informed Consent from NIH Office for Protection from Research Risks

- Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language", (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when

deficiencies are noted or when additional information will improve the consent process.

- Use of the first person (e.g., "I understand that ...") can be interpreted as suggestive, may be relied upon as a substitute for sufficient factual information, and can constitute coercive influence over a subject. Use of scientific jargon and legalese is not appropriate. Think of the document primarily as a teaching tool not as a legal instrument.
- **Describe the overall experience that will be encountered.** Explain the research activity, how it is experimental (e.g., a new drug, extra tests, separate research records, or nonstandard means of management, such as flipping a coin for random assignment or other design issues). Inform the human subjects of the reasonably foreseeable harms, discomforts, inconvenience and risks that are associated with the research activity. If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform subjects as they are recontacted or newly contacted.
- **Describe the benefits that subjects may reasonably expect to encounter.** There may be none other than a sense of helping the public at large. If payment is given to defray the incurred expense for participation, it must not be coercive in amount or method of distribution.
- **Describe any alternatives to participating in the research project.** For example, in drug studies the medication(s) may be available through their family doctor or clinic without the need to volunteer for the research activity.
- **The regulations insist that the subjects be told the extent to which their personally identifiable private information will be held in confidence.** For example, some studies require disclosure of information to other parties. Some studies inherently are in need of a Certificate of Confidentiality which protects the investigator from involuntary release (e.g., subpoena) of the names or other identifying characteristics of research subjects. The IRB will determine the level of adequate requirements for confidentiality in light of its mandate to ensure minimization of risk and determination that the residual risks warrant involvement of subjects.
- **If research-related injury (i.e. physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk (see 45 CFR 46.102[g]), an explanation must be given of whatever voluntary compensation and treatment will be provided.** Note that the regulations do not limit injury to "physical injury". This is a common misinterpretation.
- **The regulations prohibit waiving or appearing to waive any legal rights of subjects.** Therefore, for example, consent language must be carefully selected that deals with what the institution is voluntarily willing to do under

circumstances, such as providing for compensation beyond the provision of immediate or therapeutic intervention in response to a research-related injury. In short, subjects should not be given the impression that they have agreed to and are without recourse to seek satisfaction beyond the institution's voluntarily chosen limits.

- **The regulations provide for the identification of contact persons who would be knowledgeable to answer questions of subjects about the research, rights as a research subject, and research-related injuries. These three areas must be explicitly stated and addressed in the consent process and documentation.** Furthermore, a single person is not likely to be appropriate to answer questions in all areas. This is because of potential conflicts of interest or the appearance of such. Questions about the research are frequently best answered by the investigator(s). However, questions about the rights of research subjects or research-related injuries (where applicable) may best be referred to those not on the research team. These questions could be addressed to the IRB, an ombudsman, an ethics committee, or other informed administrative body. Therefore, each consent document can be expected to have at least two names with local telephone numbers for contacts to answer questions in these specified areas.

- **The statement regarding voluntary participation and the right to withdraw at any time can be taken almost verbatim from the regulations.** It is important not to overlook the need to point out that no penalty or loss of benefits will occur as a result of both not participating or withdrawing at any time. It is equally important to alert potential subjects to any foreseeable consequences to them should they unilaterally withdraw while dependent on some intervention to maintain normal function.

NIH Informed Consent Checklist - Basic and Additional Elements

	A statement that the study involves research
	An explanation of the purposes of the research
	The expected duration of the subject's participation
	A description of the procedures to be followed
	Identification of any procedures which are experimental
	A description of any reasonably foreseeable risks or discomforts to the

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	subject
	A description of any benefits to the subject or to others which may reasonably be expected from the research
	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
	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
() Research Qs	An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject
() Rights Qs	
() Injury Qs	
	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
Additional elements, as appropriate	
	A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
	Any additional costs to the subject that may result from participation in the research
	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
	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
	The approximate number of subjects involved in the study

**Appendix B--Letter of Consent to Use Material from the Policy and Procedure
Manual for Research with Human Subjects from Nova Southeastern University**

From: Barbara Sterry <sterry@nsu.acast.nova.edu>

Subject: Re: Fw: IRB manual

Date: Wed, 10 Nov 1999 13:49:14 -0500

To: Inga Hess <inga@nsu.acast.nova.edu>

Dr. Ginther:

Inga Hess, our IRB support person forwarded your request to me for response. You are more than welcome to use our IRB manual in the development of yours. We would, of course, appreciate acknowledgement. Also, if you have other questions as you go through the process, please feel free to contact me either by phone or email. I would very like to see a copy of your finished product. Finally, I apologize for taking so long to get back with you. I have been out of the office for two weeks and my hard drive crashed and am just now back in operation. Good luck as you develop your manual. The whole IRB experience for us has been quite interesting and challenging to say the least!

Regards,

Barbara Sterry