

UNIVERSITY OF ST. THOMAS
INSTITUTIONAL REVIEW BOARD
INTERNAL POLICY INFORMATION

The Mandate and Mission of the IRB

In keeping with its distinctive mission as a Catholic university (“to develop morally responsible individuals,” **Mission statement**) as well as with federal regulations (45 CFR 46), the University of St. Thomas is committed to a policy of safeguarding the dignity, rights, and privacy of all human participants of scientific research, whether such research is federally funded or not.

The commitment of the University to the protection of human participants is rooted in the conviction that both researcher and participant are “created in the image of a just and loving God” (College Vision Statement). Consequently, respect and concern for the welfare of each participant should be the investigator’s highest priority.

The mission of the Institutional Review Board at the University of St. Thomas is to assist faculty, staff and student researchers in meeting the highest ethical and professional standards for the use of human participants in scientific research.

Only the primary investigator and members of the IRB will have access to the decisions of the board. Internal deliberations of the IRB are kept confidential. Deliberation results will be communicated according to policy.

The following provisions are the policies of the University of St. Thomas IRB. Policies that are required by federal law (45 CFR 46) governing this board may **not** be amended unless federal law is amended or otherwise changed. All other policies may be amended by a majority vote of the board.

The Institutional Review Board of the University of St. Thomas is part of the office of the AVP/CAO. Research that has been reviewed and approved by the IRB may be further reviewed and disapproved by the Academic Vice President/Chief Academic Officer (AVP/CAO). However, the AVP/CAO of this committee may not approve research that has been disapproved by the IRB.

APPOINTMENT TO THE IRB

Consistent with federal regulations (45 CFR 46.107) the University of St. Thomas Institutional Review Board must have a minimum of five members but may have as many members as necessary to perform its duties adequately. These members are chosen from varying backgrounds ensuring they have the diversity, experience, expertise, and sensitivity to consider the cultural backgrounds, gender and community attitudes of all applicants ensuring that each human participant is treated with respect and their rights and welfare are protected. Members of the board will be represented of the scientific and non-scientific areas of the University. A community member who is not affiliated with the institution and who is not part of an immediate family member associated with the university is needed for compliance with Federal regulations. The board should be gender and professionally balanced. The members are to serve for no more than two three year terms.

At the end of the *first* term, renewal of the *second* term may be approved by a majority of the IRB. If an IRB member chooses not to participate in a second term he/she should notify the chair in writing at the beginning of the spring semester at the end of the first term.

The chair of the IRB is to ensure that specific members are recruited each year to ensure that the professional competence of the board is maintained.

New members will be invited by the IRB Chair and approved by the AVP/CAO

In the event that a board member has a conflicting interest in any initial or continuing review of a proposal that member cannot participate in the review of the approval process may not be present during the review or voting process. The member's

presence may be requested for information only. The minutes for that meeting should record this information.

At the discretion of the IRB, individuals, who have expertise in a special area, will be invited to assist in the review of issues which require expertise beyond or in addition to that which is available on the board.

In the review of a research proposal in which the participants are prisoners, persons under arrest, or on parole, the IRB will include a person with expertise in prison populations to advocate for and protect the rights of these potential participants. These experts do not have voting privileges.

Should there be a disagreement about a vote by the IRB any member has the right to file a dissent. The procedure is as follows:

1. When a member wishes to write a dissenting opinion regarding an IRB vote, he or she should so inform the board at the time of the IRB vote.
2. The IRB chair will inform the primary investigators of a potential dissent along with the letter regarding the outcome of the IRB deliberations.
3. The letter of dissent will be sent to the AVP/ACO along with copies to the IRB and the principal investigator within one week of the IRB vote on the proposal.
4. The chair will then file the dissent in the respective IRB file as documentation of the dissent.

Members may suspend or resign from their service prior to completion of their current term for sabbatical leave, family emergency, etc. With the exception of emergencies, written notification of suspension or resignation must be given to the IRB chair at least one month (30 days) in advance.

Members may be dismissed from the board for just cause only with the direct approval of the AVP/CAO, the IRB Chair, and a majority of the members of the IRB.

SELECTION OF THE IRB CHAIRPERSON

The chairperson of the IRB shall be a UST faculty member who has served on the board either presently or in the past. A co-chair may be selected if deemed necessary, and again with the same criteria. Nominations for the chair will be recommended from any board member during the last scheduled full board meeting of the spring semester. Self nomination is accepted. The election to this position is derived from a majority vote of those IRB members present and voting at this meeting. The chair or chair persons will serve for a period of two years and may be considered for re-election at the end of the first term of office just as other members of the board renew their terms. Renewal of the IRB chair is participant to approval by a majority of the board members

DUTIES OF THE CHAIR

- The chair will preside at all meetings. In the event that this is not an option for a meeting the members present shall appoint a member to act as chairperson for that meeting with the temporary chair having all the responsibilities and duties assigned to the chair.
- The chair or co-chair shall review all applications to determine the appropriate review category (exempt; expedited or full board)
- The chair shall oversee the timely distribution to IRB members of all full-board applications for review. Expedited and exempt proposals are subjected to the chair's discretion.
- The chair shall establish, publish and distribute a calendar containing the dates, time and place of each regularly scheduled full-board review meeting to the university community and to each IRB member.
- The chair shall provide notification of special meetings to each of the IRB members.
- The chair shall notify each IRB member at least five days in advance of a regularly scheduled meeting and at that time the agenda for the meeting is

sent along with the minutes from the last meeting. Proposals are to be sent in an adequate time frame so they will be ready for discussion by the members at the scheduled meeting.

- The chair is responsible for keeping the records of all ongoing research and for notification to the principal investigator at least two months before the anniversary date of the proposal.
- The chair is responsible for informing investigators of annual review mandates.
- The chair is responsible for monitoring all compliances with federal regulations and keeping current with federal wide assurances.
- The chair is responsible for the establishment and overseeing an IRB budget.
- The chair shall prepare and submit an annual summary of IRB activity by July 1 to the AVP/CAO.
- The chair is to appoint a secretary from the board members who is responsible for the following information: The attendance, summary of the discussion, its resolution, and overall vote is to become part of the official record. The chair is to keep a copy of the minutes along with other official IRB records.
- The chair is responsible for the maintenance of the IRB office with a systematic arrangement of files and correspondence.

THE FOLLOWING DOCUMENTS ARE MAINTAINED IN THE IRB OFFICE

(CRF 46.115)

- Copies of all research proposals reviewed, scientific evaluations that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to participants.
- Minutes of IRB meetings in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolutions

- Copies of all correspondence involving continuing review research, including all copies of communication between investigator and the IRB.

All the records required by this policy shall be retained for at least three years. IRB files shall be accessible to authorized representatives of the Office for Human Research Protection (OHRP) upon request.

The full board shall meet at least once per month during the academic year with the option of canceling a meeting if there are no protocols to review. The cancellation of this meeting may not occur more than ten days prior to the scheduled date.

A quorum consists of a majority of the present membership of the IRB. This quorum must be present for voting on a full-board proposal.

REVIEW AND CONSIDERATION OF PROTOCOLS:

1. Whenever possible and desirable, the principal investigator or a designated alternate shall be present at that portion of the meeting in which his/her proposal is under consideration for clarification of relevant portions of the project or protocol.
2. Members of the IRB are authorized to ask any questions pertaining to the study in order to reach a conclusion regarding its risks, benefits, safety, and protection of human participants.
3. After an adequate period of discussion of the research protocol the Chair asks for a “motion to consider” at which point any IRB member may move for one of the applicable decisions for that particular project.
4. The chair of the IRB will notify investigators in writing of the results of the review. The range of possible judgments and corresponding actions are as follows:
 - **Approval:** The proposal, consent forms and other documentary materials are satisfactory as presented and the investigator may begin the project immediately.

- **Conditional approval:** The project is not satisfactory as submitted. The investigator must make modifications and/or alterations to protocol and/or to the consent form or form(s) necessary as recommended by the board before the research may be approved. The chairperson shall communicate in writing the findings of the IRB and the necessary recommendations for approval. The revisions, modifications and all other required changes of the proposal must meet the satisfaction of the IRB Chairperson (acting on behalf of the IRB) before the project is initiated.

If the investigator does not respond to the notification by the IRB of the required changes within thirty (30) calendar days of received CONDITIONAL APPROVAL, the proposed project must be resubmitted for full board review consideration at the next regularly scheduled IRB meeting.

- **Deferral:** There is insufficient information to reach any definitive conclusion for approval or disapproval. The investigator will be asked to revise the protocol and **resubmit** the proposal for full board review at a later meeting.
- **Disapproval:** The protocol places participants at an unacceptable risk relative to the benefits. The research as designed and described is not suitable for the involvement of human participants and may not proceed. Notification to the investigator will be in writing containing all of the suggestions made by the IRB.
If the primary investigator chooses, the proposal may be revised and resubmitted at a later date.

Every responsible effort will be made to assist the investigator in bringing a non approved project into compliance for IRB approval. However, meeting deadlines and time demands are entirely the responsibility

of the investigators submitting the proposals.

- **Dissent policy** Should there be a disagreement about a vote by the IRB any member has the right to file a dissent. The procedure is as follows:
 1. When a member wishes to write a dissenting opinion regarding an IRB vote, he or she should so inform the board at the time of the IRB vote.
 2. The IRB chair will inform the primary investigators of a potential dissent along with the letter regarding the outcome of the IRB deliberations.
 3. The letter of dissent will be sent to the Vice president for Academic Affairs along with copies to the IRB and the principal investigator within one week of the IRB vote on the proposal.
 4. The chair will then file the dissent copy and other written records in the respective IRB file as documentation of the dissent.

DOCUMENT 11
FOR THE INVESTIGATOR

THE MANDATE AND MISSION OF THE IRB

In keeping with its distinctive mission as a Catholic university (“to develop morally responsible individuals,” **Mission statement**) as well as with federal regulations (45 CFR 46), the University of St. Thomas is committed to a policy of safeguarding the dignity, rights, and privacy of all human participants of scientific research, whether such research is federally funded or not.

The commitment of the University to the protection of human participants is rooted in its conviction that both researcher and participant are “created in the image of a just and loving God.” (College Vision Statement) Consequently, respect and concern for the welfare of each participant should be the investigator’s highest priority.

The mission of the Institutional Review Board at the University of St. Thomas is to assist faculty, staff and student researchers in meeting the highest ethical and professional standards for the use of human participants in scientific research.

DEFINITIONS, PRINCIPLES AND CRITERIA FOR REVIEW

DEFINITIONS

The following terms frequently occur throughout this manual. The definitions applicable to these terms are established by the **Code of Federal Regulations**.

- **RESEARCH** means a systematic investigation, including the development, testing and evaluation designed to develop or contribute to universal knowledge (45CFR.45.102).
- **HUMAN PARTICIPANT** a living individual about whom an investigator (whether a professional or a student) conducts research and obtains: a. data through intervention or interaction with an individual; b: identifiable private information. (45CFR 46.102(f)).
- **VULNERABLE PARTICIPANTS** are classified as children, soldiers, fetuses, prisoners, mentally incompetent children and adults, economically or

educationally disadvantaged persons, and those with Acquired Immune Deficiency Syndrome (AIDS) or are HIV positive.

- 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. (45CFR 46.102(1)).
- INFORMED CONSENT means the process through which participants are made aware of the purpose, risks, and benefits of a specific research investigation, as well as the voluntary nature of participation in the study. (45CFR 46.116) explains the general requirements for informed consent. (45CFR 46.117) explains the documentation for informed consent.
- UNEXPECTED ADVERSE EXPERIENCES means any adverse experience that is neither identified in nature, severity, or frequency of risk in the information that is provided for IRB review or not mentioned in the consent form.

PRINCIPLES

The moral principles guiding the IRB review of research proposals are governed by the Nuremberg code (1949), the World Medical Association's Declaration of Helsinki (1964; 1975; 1983; 1989) and the Belmont Report published by the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research (1979).

Three basic principles of overriding importance are:

1. Respect for Persons: human participants must be treated as autonomous and able to make responsible choices. This principle leads to the requirement of informed voluntary consent
2. Beneficence: participants must be protected from harm and their well being must be secured. This principle leads to the requirement that the benefits to participants or to humanity generally must be judged to outweigh the risks to participants.
3. Justice: the risks and benefits of research must be distributed fairly without creating differences in treatment for ethnic, racial, religious,

sexual or age-defined classes. This principle leads to the requirement that investigators take care not to exploit **special classes of persons** less able to refuse participation in research. (Refer to definition of vulnerable populations).

REVIEW CRITERIA

Research proposals will be reviewed for conformity to the aforementioned principles in both the design and implementation of the research project itself.

Since the IRB is concerned foremost with the protection of the well-being, dignity, and rights of each human participant in the research. The following questions should be answered:

1. Are human participants adequately protected from exposure to more than **minimal risk** of harm, whether physical or psychological? (Found only in exempt or expedited reviews).
2. In the research where human participants are exposed to greater than minimal risk do the benefits of the research outweigh the burdens imposed on human participants whether they are physical or psychological? Found in **full board review only**.
3. Whether and how adequately human participants in the research are **voluntary and informed?**
4. Are the **privacy** rights of each human participant protected?
5. Are **vulnerable populations** children, soldiers, fetuses, prisoners, mentally incompetent adults and children, the economically or educationally disadvantaged, and those who have AIDS or are HIV positive protected from either physical or psychological harm?
6. Does the proposed research fairly distribute both risks and benefits between ethnic, racial, religious, sex and age- defined categories?

TYPES OF REVIEW

Before beginning research, investigators must:

1. determine under which category their research falls
2. complete the application form
3. attach all necessary documentation (consent and assent forms)

Submit these forms along with all the research information to the chair of the Institutional Review Board.

All research proposals involving human participants fall under one of the following three categories:

EXEMPT REVIEW: Research is of minimal or no risk; requires review by the IRB chair or the chair's designee(s)

Criteria for an exempt review are:

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.

1. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.
2. Research involving survey, interview and observational procedures, if all of the following conditions exist:
 - a: responses and observations are recorded in such a manner that the human participants cannot be identified, directly or through identifiers linked to the participants.
 - b: if the participant's responses, do not become known outside the research, or if they do not place the participant at risk of criminal or civil liability or could be damaging to the participant's financial standing or employability.

c: if the research does not deal with sensitive aspects of the participant's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

3. Research involving survey or interview procedures are exempt when the respondents are elected, appointed as a public official or a candidate for public office.

4. Research involving the collection or study of existing data, documents, records or specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

EXPEDITED REVIEW

Research with human participants involving no more than minimal risk may qualify for expedited review. Minor changes in previously approved research projects may also be considered for expedited review. In cases of doubt about whether a specific research proposal qualifies for expedited review (as to whether the following guidelines apply) the investigator should contact the chair of the IRB (45 CFR 46.110 federal guidelines).

The following are some of the examples of research qualifying for expedited review:

1. Voice recordings made for research purposes such as investigations of speech defects.
2. Moderate exercise by healthy volunteers.
3. The study of existing data, documents, records, or specimens.
4. Research on individuals, group behavior, or the character of individuals, such as studies of perception, cognition, game theory, or test development where the investigator does not manipulate participants' behavior and the research does not involve stress to participants.

5. Collection of hair and nail clippings, in a non-disfiguring manner; deciduous teeth and permanent teeth if patient care indicates a need for extraction.
6. Collection of excreta and external secretions including sweat, uncannulated saliva, placental removal at delivery and amniotic fluid at the time of rupture of the membrane prior to or during labor.
7. Recording of data from participants 18 years of age or older using non-invasive 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 in to the participant or an invasion of the participant's privacy. It includes such procedures as weighing, testing sensory acuity, electroencephalography, electrocardiography, thermography, detection of naturally occurring radioactivity, diagnostic echocardiography, and electro-retinography. It does not include exposure to electromagnetic radiation outside the visible range (e.g. x-rays, microwaves).
8. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two (2) times per week, from participants 18 years of age and older who are in good health and not pregnant.
9. Collection of both supra-and sub-gingival 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.
10. Research on an investigational new drug or an investigational device where exemption is not required.

If these exemptions are not met then the proposal will revert to full board review

FULL IRB BOARD REVIEW

HUMAN PARTICIPANT RESEARCH involving more than minimal risk to the participant requires review by the full IRB using a risk/benefit analysis. All research using **children** or other identifiable **vulnerable populations** (soldiers, fetuses, prisoners, mentally incompetent adults and children, economically or educationally disadvantaged persons and those with HIV syndrome or AIDS and the use of deception requires review by the full board.

Prisoners are identified as any individual involuntarily confined or detained in a penal institution. This applies to individuals sentenced under criminal or civil statutes and those who are detained in other facilities by virtue of statutes, commitment procedures, awaiting sentencing, arraignment, or trial. Individuals on probation or under court orders are also placed in this category.

Research involving survey, interview or observational procedures require full board when any of the following exist:

1. The recording of the responses, to the survey, interview and observations could identify the participants directly or indirectly through identifiers.
2. The participant could be at risk for criminal or civil liability or be damaging to his financial status or employability .
3. That the research deals with sensitive aspects of the participant's behavior, conduct, sexual behavior, alcohol or drug use.

ALL research involving deception requires full board review.

Proposals for **full board** review must be in the IRB office two (2) weeks before the next board meeting.

COURSE RELATED RESEARCH

- Class Protocols for Research Methods Courses
All student research with human participants is subject to review by the IRB prior to initiation of the research tasks.

Classroom protocols are defined for two types of classroom research activity:

1. The entire class may be doing the same assignment (e.g., all students are collecting data on a survey form which they will later analyze together as a class).
2. Each student is doing individual research within the parameters of a classroom assignment (e.g., students must create a research project, according to specifications delineated by the instructor, and carry it out).

Any consent forms used must include the instructor's name, department, telephone number and e-mail address so that potential participants may contact him or her with questions regarding the research project.

When the overall objective of a class assignment is to learn about how research projects are designed and conducted, and analysis of the data will occur for learning purposes only, a request for approval for a "Class Protocol" should be filed with the IRB. The objective is to ensure that the class assignment includes appropriate precautions for protecting the human participants involved in the class exercise.

Depending on the scope and nature of the assignments, the IRB may require minor modifications in participant population or topic areas for research to ensure protection of the human participants.

If the IRB has granted full board approval for class protocols that continue along the same theme for subsequent semesters or are offered numerous times during the academic year, than annual updates are required to ensure that the approved guidelines are maintained. It is the responsibility of the **researcher** to complete the annual report and submit the report to the IRB.

- Other student research

All other student research must be directed by a faculty advisor who assumes responsibility for the protection of the human participants involved in the project. Independent class projects, senior theses, undergraduate research opportunity programs, master's projects etc., require approval by the student's academic advisor as part of the application for approval by the IRB.

IRB ACTION AND NOTIFICATION

A: Duration of Review: Compliances for notification to investigators

- **Exempt review:** Investigators will receive written notification of the results of the IRB review of their research proposal no more than seven (7) days after submission.
- **Expedited review:** Investigators will receive written notification of the results of the IRB review of their research proposal no more than twenty-one (21) days after submission.
- **Full Board review:** Investigators will receive written notification of the results no more than seven (7) days after the full board meeting date. Dates of these meetings are listed on the web page link.

B. Categorical decisions of the IRB Board

The chair of the IRB will notify investigators in writing of the results of the review.

The range of possible judgments and corresponding actions are as follows:

- **Approved:** The proposal, consent forms and other documentary materials are satisfactory as presented and the investigator may begin the project immediately.
- **Conditional approval:** The project is not satisfactory as submitted. The investigator must make modifications and/or alterations to protocol and/or to the consent form or form(s) necessary as recommended by the board before the research is approved. The chairperson shall communicate in writing the findings of the IRB and the necessary recommendations for approval. The revisions, modifications and all other required changes of the proposal must meet the satisfaction of the IRB Chairperson (acting on behalf of the IRB) before the project is initiated.

If the investigator does not respond to the notification by the IRB of the required changes within thirty (30) calendar days of receipt the proposed project must be resubmitted for full board review consideration at the next regularly scheduled IRB meeting. The

letter of notification from the chair will convey these stipulations and the time limit.

- **Deferral:** There is insufficient information to reach any definitive conclusion for approval or disapproval. The investigator will be asked to revise the protocol and **resubmit** the proposal for full board review at a later meeting. A written letter with the information needed for approval of the proposal will be sent to the investigator.
- **Disapproval:** The protocol places participants at an unacceptable risk relative to the benefits. The research as designed and described is not suitable for the involvement of human participants and may not proceed. Notification to the investigator will be in writing containing all of the suggestions made by the IRB.
If the primary investigator chooses the proposal may be rewritten and submitted at a later date.

*Every responsible effort will be made to assist the investigator
In bringing a non approved project into compliance for IRB
approval.*

*However, meeting deadlines and time demands are entirely the
responsibility
of the investigator submitting the proposals.*

Confidentiality:

The primary investigator and members of the IRB will have access to the decisions of the board. Internal deliberations of the IRB committee are kept confidential. Deliberation results will be recorded and kept in the IRB files.

Continuing review:

All approved expedited and full board ongoing research projects involving human participants require an annual review. Occasionally, projects will require more

frequent review, for example, when there have been reports of injury or unexpected adverse experiences.

A: Reporting procedure:

Annual reports from investigators are due one year after the project approval date.

The chair will inform the investigators in writing two(2) months prior to impending annual review dates. At that time, reporting forms will be made available to relevant investigators.

B: Failure to file an annual report:

If no annual report is filed within a thirty (30) day period from the annual report due date, approval will expire on the anniversary date.

SPECIAL CONSIDERATIONS

A: Changes in Approved Research Protocols:

Once approval has been granted for a protocol and consent documents, the principal investigator is responsible for informing the IRB of any proposed changes in population, recruitment plans, research procedures, study instruments, study site, or major personnel.

B: Unusual Event Reporting:

1. Reporting Requirements: Investigators are reminded that all “unexpected adverse experiences” should be reported to the IRB. This policy applies to all research involving human participants.
2. What to Report: “Unexpected adverse experience” means any adverse experience that is neither identified in nature, severity, or frequency of risk in the information provided for review by the Board and not mentioned in the consent form.
3. Unusual Events: Sometimes the event is unrelated to the research protocol but will have an effect on the research participant (e.g. a misunderstanding in the consent documentation, a breach of confidentiality, a stolen computer with research data, etc). These unusual events should be reported promptly to the IRB so that a response may be prepared in the event a participant or legal authority inquires about the study. An adverse experience or an unusual event must be reported to the IRB within ten (10) working days of the incident.
4. Content of the Report: Written reports are required by the IRB whether the study sponsor requires such a report or not.
5. All Written Reports should include:
 - a. An explanation of the event, including date and participant description and if anything is being done to rectify the situation. The report may include a standard report form as required by the study sponsor.
 - b. A cover letter from the principal investigator commenting on the event and describing the likelihood that the event may occur again. This

statement should include an explanation of the investigator's reaction to the event in terms of implications for future participants.

- c. If the current consent form does not contain the new risk information a revised consent form must be written.
- d. Should the IRB learn about a problem with a human participant research study from a source other than the primary investigator, the IRB chair will investigate by sending a letter to the primary investigator, the research advisor (if applicable,) and the department chair documenting the adverse event.
- e. The primary investigators and the advisor (if applicable) have primary responsibility for resolving the situation.
- f. A written report with the information of the resolution and the final outcome shall be sent to the IRB.
- g. The IRB will review all adverse experience reports to ensure that the adverse events do not change the risk/benefit ratio. If a pattern of unanticipated events should emerge the IRB may require changes in the protocol or revisions in the consent form.

If the issues cannot be satisfactorily resolved at the department level the IRB will refer it to the Executive Vice President /Chief Academic Officer of the University.

All documentation regarding the problem will be maintained in the file on the study.

C: Anticipated Side Effects:

Events that were anticipated in the protocol and mentioned in the original consent form should be reported to the IRB at the time of annual review and renewal. The IRB may require changes in protocol or revisions in the consent form. The principal investigator should exercise discretion as to whether additional participants could be entered into a study, or whether current participants should be continued, based on the information contained in the event report. The IRB may temporarily suspend any study while the event is reviewed. If the IRB determines that the risks to

participants have increased dramatically, a full review of the study may be required. The IRB may permanently terminate a study based on an adverse experience.

D: Recruiting for Research Participants

The IRB must review all means of recruiting participants for participation in a research study. This advertisement will be reviewed and approved by the Board to determine that the procedure for recruitment affords adequate protection and that it is not misleading to potential participants.

Advertisements should be submitted for review at the time of initial submission of an application, or at such time as the principal investigator chooses to use advertisements as a means of recruiting participants.

Advertising information is limited to:

- Name and contact information of the investigators (identify university by name)
- Purpose of the research
- General eligibility criteria
- Straightforward and truthful description of benefits. (Payment or none)

No claims should be made either implicitly or explicitly that the research is superior to any current practice. If the participants are to be reimbursed or paid for their participation in the study the IRB is required to consider the uniqueness of each study and determine the appropriateness of the payment for that project. This requires the board to consider whether the paid participants are recruited fairly; informed adequately; and paid appropriately.

The Board must take into consideration any payments which appear to create a coercive situation. (e.g. one in which the participants might agree to participate or continue to participate against their better judgment).

The consent form must clearly describe a detailed account of terms of payment and conditions under which participants would receive partial payment or no payment, as in situations involving early withdrawal from their participation.

E: Research Involving Children as Participants:

Federal guidelines include specific regulations regarding the inclusion of children in research protocols. Research that is considered to be of greater than minimal risk must include a balance of risks and benefits in order to allow participation in a research project in order for a minor child to be included. There must be direct personal benefit to the child to allow participation in a research project that has an element of risk. Minor children are individuals who have not attained the legal age for consent (in this jurisdiction attaining the age of eighteen (18)). If a research protocol, considered to be greater than minimal risk, is presented and there is no demonstrated benefit to the child, the IRB cannot allow the inclusion of the child in the study.

Written parental consent is required for all research involving children, with few exceptions. The conditions under which a “waiver of parental consent” can be granted are cases in which the research will yield great benefit to the population being studied, and when the process of gaining parental consent will pose additional risk to the potential participant. In research that is considered greater than minimal risk, both parents’ signatures are required if the second signature is reasonably available.

Assent of the child is required in all research involving children who have the capacity to comprehend aspect of the research project. Those children who are ten (10) years of age or older, with normal intelligence, must be offered the opportunity to participate in the informed consent process and offered the opportunity to sign a form documenting the “assent” to participate. Documentation of “assent” is required by the IRB either in a line for the signature of the child or in a separate form. Reasonable effort must be made on the part of the investigator to tailor the consent form for comprehension by the child participant.

F. Prisoners as Research Participants:

The Department of Health and Human Services (DHHS) has the authority to govern any biomedical or behavioral research using prisoners or parolees to the following guidelines: Only research designated and designed as no more than minimal risk is suitable for prisoner research.

- a. The prisoner is able to participate in the study without the intervention of fraud, force, deceit, duress or any other ulterior form of coercion.
 - b. The confidentiality of participation and the subsequent data can be adequately maintained.
 - c. If there is any possible advantage or risk to the prisoner participant it can be no greater than that of the general population.
 - d. The selection and control participants are chosen from all who meet the criteria of the research without bias.
- The consent form should clearly state that participation in the project was obtained without coercion, is freely consented, has little or no benefit to the participant
 - The language of the consent form is written clearly so as to be understood by the participants regardless of the level of education.
 - It must be clearly stated that participation in this research has no effect on the parole of the prisoner.
 - The consent form will clearly state that the institution has given its permission for its inhabitants to participate in the research.
 - A separate consent form is obtained from the institution for permission to conduct the research by the investigator.

A further list of guidelines for possible studies can be obtained in DHHS (SEC 46.305).

G: Students as Research Participants:

If an instructor, for a scientifically justified reason, wants to include his/her students as research participant in a project, special consideration of recruitment techniques are in order. Of primary concern is the process by which student participants are assured of their participation not influencing class standing or grades. Of secondary concern is that they may decline participation without jeopardy. If at all possible researchers should avoid using their own students if another

population of participants is equally suited to the research. As examples –another class section not taught by the professor, recruitment done by another professor or blinded/coded data collected by an associate so that the participants are not identified to the instructor.

Unless the research question is directly related to class material, or the study process is used as a teaching opportunity, such as in a research methods class. The IRB discourages the use of significant class time to recruit participants to complete the research.

Participation for credit should be one of a number of other options available to earn the same amount of extra credit. The number of points awarded should not be sufficient to increase the grade by a whole step—such as from a B to an A. The information about the extra credit should be included in the application.

H: Employees as Research Participants:

The IRB is concerned about the use of colleagues, peers or subordinates as participants in a research project. The employees may have a fear of retribution, demotion, termination, coercion, undue influence, along with a breach of confidentiality.

I: Conflict of Interest Disclosures:

The principal investigator must disclose in the Human Participant consent form if the principal investigator has an interest in a company that may be affected by the research.

Determination of “interest” must be communicated to the IRB so that assurances of compliance with this policy can be enforced in the design of the consent form for this particular research project. Full and complete disclosure of the interests of the researchers is the only approved means for pursuing informed consent from research participants.

J Non Compliance:

The primary task of the Internal Review Board of St. Thomas is not to “police” research. However, investigators are reminded that the initiation and or continuation of non-approved research will be reported, should it prove necessary, to the AVP/CAO, whose office is the institutional home of the IRB.

In order to determine that all substantive and relevant changes in protocol and /or consent documents are being reported, and in order to verify compliance with federal regulations, the IRB shall have the authority to physically inspect any research premises or review non-confidential research document relating to the protocol and procedures being used in human participant research experimentation. Generally the investigator will be asked to provide copies of relevant and necessary documents for IRB review. Such document requests are in addition to those generated in an annual review process. In most cases, this will occur when there is an indication that a substantive change is in effect which has not been reported. Failure to comply with such an IRB request for information may result in suspension or termination of IRB approval of research.

K. Suspension or Termination of IRB approval

In accordance with the Code of Federal Regulations
(45 CFR 46.113)

An IRB shall have the authority to suspend or terminate approval of research that is not being conducted in accordance with the requirements of the IRB or that has been associated with unexpected serious harm to participants. Any suspension or termination of approval shall include a statement of the reasons for the action of the IRB and shall be reported promptly to the investigator, appropriate institutional officials, and the Office for Human Research Protection.(OHRP).

Failure to comply with IRB directives, regulations and procedures, including annual reports, changes in protocol, consent forms, and other requests for information or compliance from the IRB Chair will result in one or more of the following actions:

- Project termination

Investigators and their staff and assistants are prohibited from involving human participants in the research project until formal IRB approval or re initiation is obtained. Such approval may be sought at the next available regularly scheduled meeting of the IRB, or at a special meeting called at the discretion of the Chair.

- Interruption of Research Support

An additional consequence of non-compliance can be the interruption of grant funds (internal or external in origin) allocated to that research project. Such “freezing of funds” will continue until the project and its investigators are in compliance according to the regulations as determined by the Internal Review Board.

- Report to Federal Agencies

In some cases the University is required to report to the Office of Human Research Protection (OHRP) any termination of a project due to non-compliance with IRB regulations and directives. Further, such non-compliance is reportable to the Federal Agency supporting the non-compliant research project.

L: *Appeal Procedures*

There are no procedures set up for a formal appeal associated with IRB review. The IRB is not a judicial body, but a review board empowered to consider and uphold the rights, welfare, and protection of human participants in research. Approval for research which has been suspended or terminated can be re-instated with evidence that the protocol or project can secure IRB approval. Similarly, a disapproved project need only be altered so that it can secure approval.

THE FOLLOWING DOCUMENTS ARE MAINTAINED IN THE IRB OFFICE
(CRF 46.115)

- Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to participants.
- Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB, the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controversial issues and their resolutions
- Copies of all correspondence involving continuing review research, including all copies of communication between investigator and the IRB.

All the records required by this policy shall be retained for at least three years. All records shall be accessible for inspection and copying by authorized representatives of the Office of Human Research Protection (OHPR) after termination of the research study.