INSTITUTIONAL REVIEW BOARD: POLICIES AND PROCEDURES

RIGHTS OF HUMAN SUBJECTS | APRIL 2022

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DALLAS THEOLOGICAL SEMINARY

AGENDA

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WHAT IS THE INTSTITUTIONAL REVIEW BOARD?

- The IRB at Dallas Theological Seminary was established in accordance with federal, state, and Seminary regulations to review all research involving human subjects and as such is guided by the highest ethical standards in the industry.
- The IRB is charged with the task of ethically protecting the rights and welfare of all human subjects in any research conducted under the aegis of DTS.
- The three basic ethical Principles that serve as the guidelines for DTS's IRB are derived from the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1978) and include:
  - **(a) Respect for persons**
  - **(b) Beneficence**
  - **(c) Justice**

WHAT IS INSTITUTIONAL RESEARCH & EFFECTIVENESS?

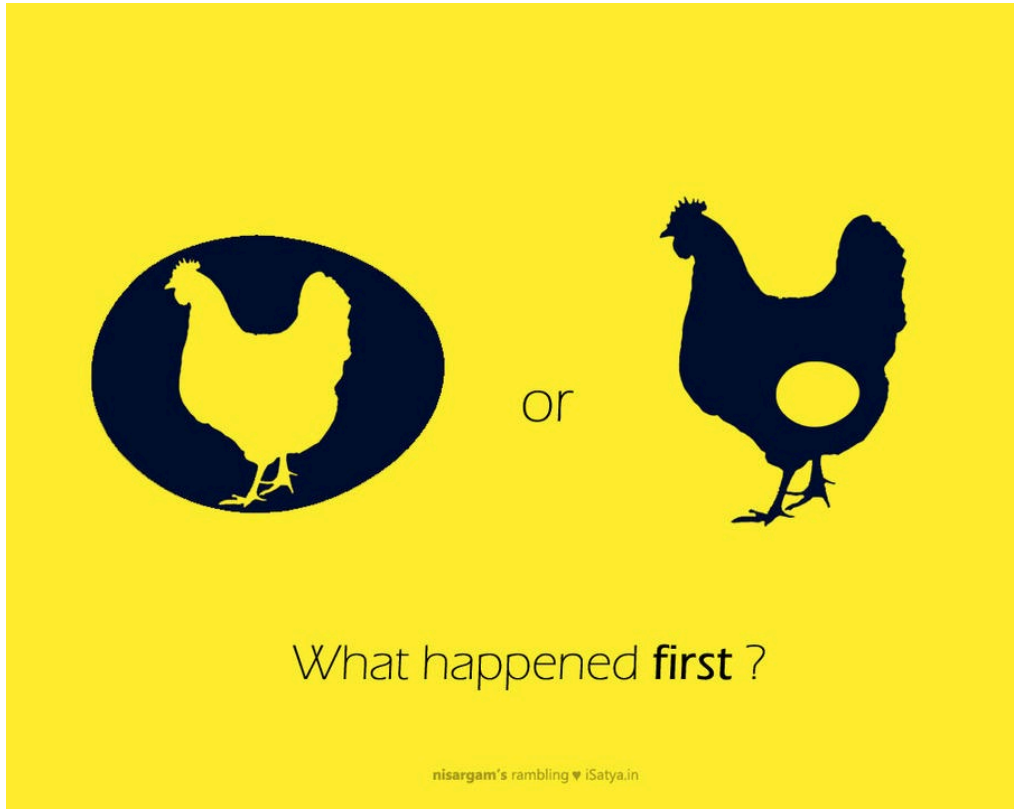
Institutional Research (IR)

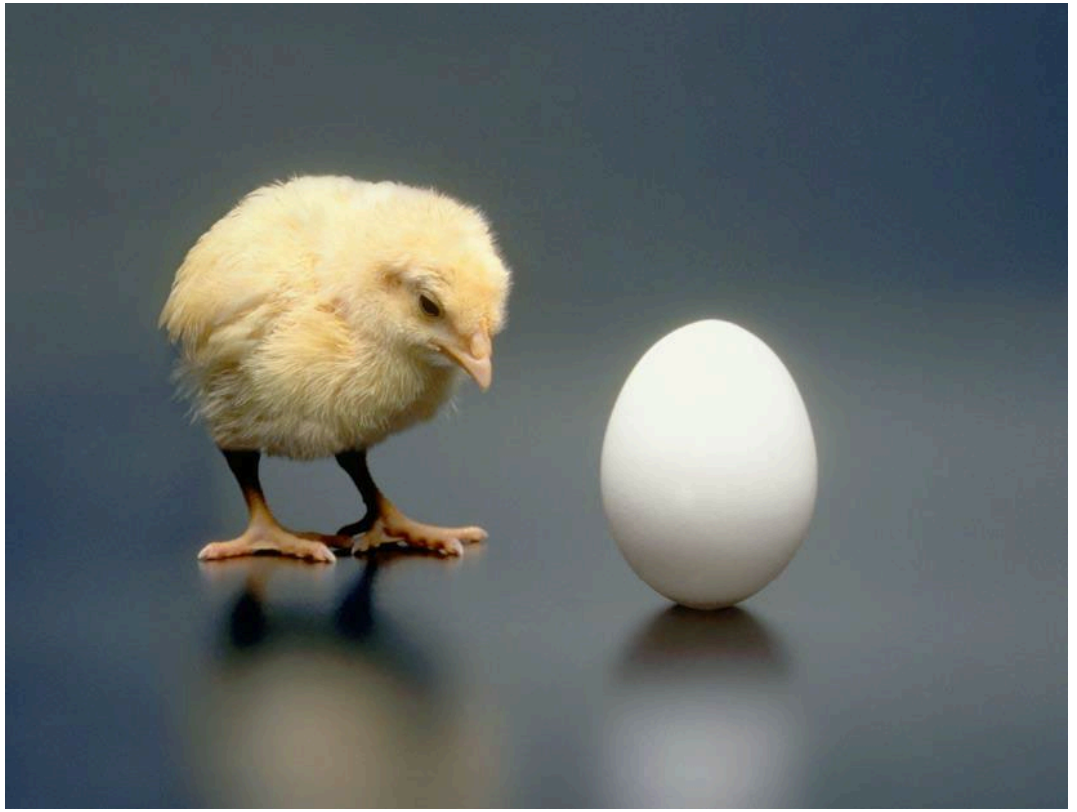
Institutional Research (IR) oversees the collection, analysis, interpretation and visualization of data used for strategic decision making, assessment and federal reporting per SACS COC & QEP accreditation guidelines.

Institutional Effectiveness (IE)

Institutional Effectiveness (IE) partners with academic & non-academic programs and services to ensure that data-driven continuous improvement solutions are implemented with fidelity to promote the efficiency, effectiveness and sustainability of Dallas Theological Seminary.

WHAT IS THE CONNECTION BETWEEN IR&E & IRB?





The Office of Institutional Research and Effectiveness (IR&E) oversees the Institutional Review Board (IR&B).

WHAT IS THE POINT OF IRB?

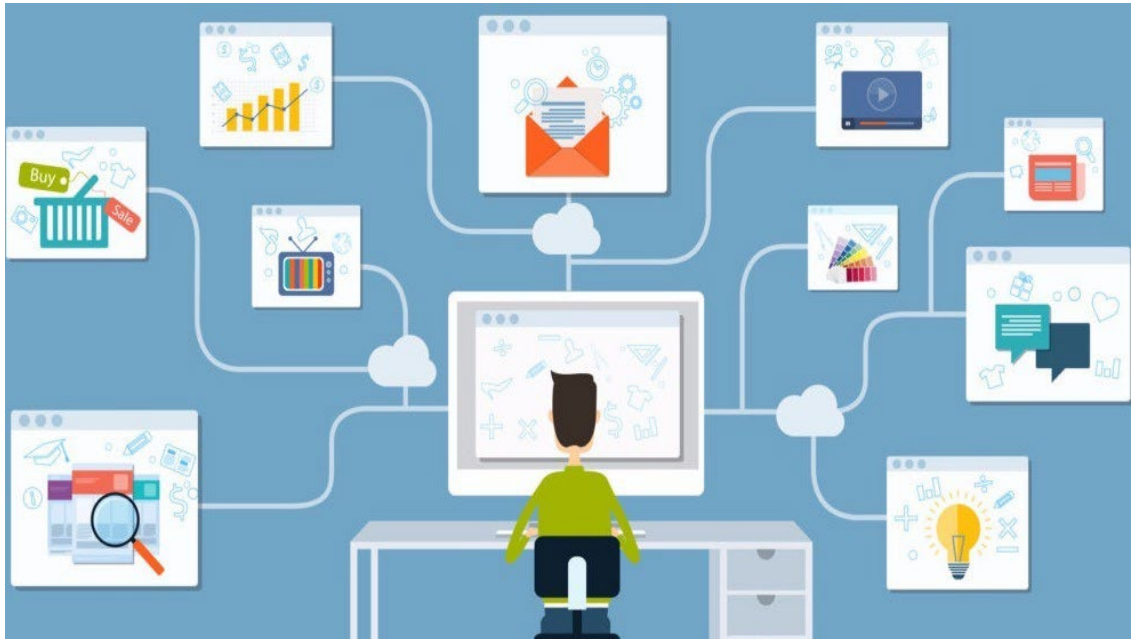
- The mission of the Office of Institutional Research & Effectiveness (IRB) Institutional Review Board is to protect the rights and welfare of human participants in research by reviewing all proposed research to be conducted by or with faculty, staff, and/or students of Dallas Theological Seminary and to ensure that participants are treated in an ethical manner that is also in compliance with federal regulations and the principles outlined in the Belmont Report.

WHAT IS THE FUNCTION OF IRB ?

- It is the policy of Dallas Theological Seminary that all research involving human subjects be reviewed by the IRB.

- Researchers are not permitted to conduct research with human subjects until the IRB has reviewed and approved the research protocol.

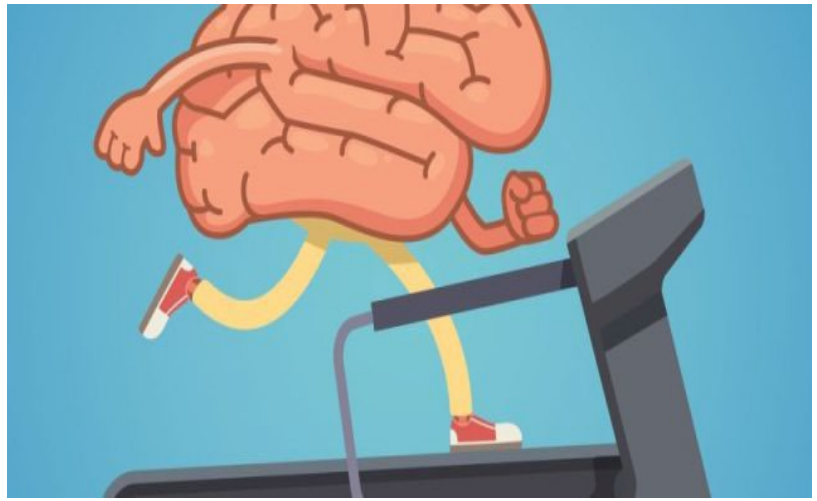
- This means that the researcher(s) cannot have any contact with potential subjects (including recruiting participants and obtaining consent) and researcher(s) cannot begin the research process until the proposal has been approved, although researchers do have permission to contact organizations from which subjects will be recruited.



WHAT ARE "TOP 5" IRB ABBREVIATIONS?

Federal regulations and Dallas Theological Seminary policy use the following abbreviations:

- **IRB** Institutional Review Board
- **IR&E** Institutional Research & Effectiveness
- **HHS** Department of Health and Human Services
- **HIPAA** Health Insurance Portability &Accountability Act
- **CFR** Code of Federal Regulations
- **OHRP** Office for Human Research Protection
- **PI** Principal Investigator



WHAT IS RESEARCH?

DEFINITIONS:

Research *means* a systematic investigation—including research development, testing, and evaluation—designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purpose of the policy and procedures, whether or not they are supported or funded under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Department or Agency 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.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual, or (b) identifiable private information.

Intervention includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes (e.g., cognitive experiment).

Interaction includes communication or interpersonal contact between investigator and human subject (e.g., a telephone interview).

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 he or she can reasonably expect will not be made public (e.g., 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) in order for obtaining the information to constitute research involving human participants.

WHAT IS MINIMAL RISK?

DEFINTITIONS

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.

IRB means an institutional review board established in accord with and for the purposes expressed in this policy.

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.

Vulnerable population means children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, individuals who are unable to give informed consent due to a physical or mental condition, or individuals whose circumstances may make them especially vulnerable to coercion (e.g., probationers).

Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures that provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. Prisoners receive additional protections under 45 CFR 46, Subpart C.

WHAT IS ASSENT?

Child means a person who has not yet attained the age of consent to treatments or procedures involved in the research, under the applicable laws of the jurisdiction in which the research will be conducted. Children receive additional protections under 45 CFR 46, Subpart D.

Parent means a child's biological or adoptive parent.

Guardian means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

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

Permission means the voluntary agreement of parent(s) or guardian to the participation of their child or ward in research. xvii. Adverse effect means an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (e.g., subject becomes upset following completion of a depression questionnaire or subject experiences intestinal bleeding associated with aspirin therapy) that is directly or indirectly due to participation in a research study.

WHAT IS A STUDENT PROJECT?

Definitions:

IRB Liaison (or IRBL) is the member of a particular college who is a current or alternate member of the IRB and serves as a reviewer on proposals submitted by the University. Each campus' IRBL also serves as a reference on IRB matters (e.g. proposals, submission) for faculty and students on his/her campus (or division) and throughout the Dallas Theological Seminary system as needed.

Principal Investigator is the person who leads the project and is ultimately responsible for all aspects of it. On most projects, the term has the same meaning as "primary researcher."

Student project means a study in which a student investigator (individually or as part of a group) gathers or analyzes information in a systematic manner, primarily for pedagogical purposes. It is not intended to contribute to generalizable knowledge and is not to be presented outside the class in which the research is being done or published/disseminated (including publication on the Internet) in any way, presented, archived, or compiled with similar research for later publishing or presentation. Research conducted for a senior project, master's thesis or seminar project does not fall under this definition.

Institutional research (or quality improvement research) is a study that is designed to obtain information to assist in the administration of the University. Institutional research provides information for administrative planning, policy making, decision making, and includes examinations of institutional effectiveness. Institutional research is specifically defined as those data collection and interpretation efforts that: (a) will not be shared outside of the University environment; (b) will not be disseminated to other professionals or the public in any forum; (c) presents no more than "minimal risk" (as defined by Federal regulation); (d) is not intended to produce "generalizable knowledge"; and (e) contains no identifiers in the data that might compromise an individual's confidentiality. Institutional efforts meeting this definition are not subject to the IRB policy and procedures.

Training refers to a process approved by the University, and required by federal regulations, to instruct investigators in the conduct of research involving human participants. Some studies may fall under the regulations promulgated by the FDA (21 CFR 50). These will generally be studies that involve the testing of an investigational medication or a medical device. Refer to 21 CFR 50 for specific definitions regarding these studies. Some FDA definitions differ from the above HHS definitions.

WHAT ARE HUMAN SUBJECTS RIGHTS?

In 1974 The United States Department of Health and Human Services delineated a set of uniform specific regulations (i.e., Code of Federal Regulations, Title 45, Part 46) to provide protection to human subjects rights and welfare when engaging in research. All research that includes the use of human subjects and/or private information about humans must comply with all of the regulations in 45 CFR 46.

Hence, the document is divided into with five subparts:

A: Protection of human subjects
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subparta

B: Pregnant women, fetuses, and neonates
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartb

C: Protection of prisoners
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartc

D: Protection of children
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html%23subpartd

WHAT IS THE BELMONT REPORT?

In September of 1978, after a four day extensive conference, the ***National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research submitted The Belmont Report***, which encompasses the basic ethical principles that govern acceptable conduct in any research that involves human subjects.

In essence, the contents of The Belmont Report are designed to aid researchers in resolving ethical dilemmas that arise when conducting research with human subjects. The three essential requirements for conducting research ethically are as follows:

Respect for persons encompasses a recognition of a person's autonomy and personal dignity, and a person's right to be protected should he or she have a diminished autonomy

Beneficence necessitates that researchers protect human subjects from harm by clearly outlining any expected benefit to the participant and taking action to minimize possible risks of harm to the participant.

Justice requires the promotion of equity in human subjects research

WHAT IS HIPAA?

All personal health information of participants collected by researchers must be protected by the **Health Insurance Portability and Accountability Act (HIPAA).**

The Department of Health and Human Services' Office for Civil Rights is responsible for enforcing the Privacy and Security Rules outlined by HIPAA.

The HIPAA Privacy Rule provides federal protection for personal health information held by covered entities and gives patients rights with respect to that information.

WHAT ARE HIPAA PRIVACY RIGHTS?

HIPAA is relevant for researchers when working with participants involved in clinical (i.e., physical or mental health) research or services.

HIPAA requires that informed consent forms for research studies include extensive detail on how the participant's protected health information will be kept private and that specific guidelines are followed for the storage and transmission of personal health information.

WHAT IS DE-IDENTIFIED DATA?

According to HIPAA's privacy rule, the information in the following list is considered director identifiers. In order for data to be de-identified, none of this information can be collected:

i. Names
ii. Geographic area (including city, state, and zip)
iii. Elements of dates
iv. Telephone numbers
v. Fax numbers
vi. Email addresses
vii. Social security numbers
viii. Medical records
ix. Prescription numbers
x. Health plan beneficiary numbers
xi. Account numbers
xii. Certificate/license numbers
xiii. Automobile VIN and serial numbers
xiv. License plate numbers
xv. Device identifiers/serial numbers
xvi. Web URLs
xvii. Computer IP address numbers
xviii. Biometric identifiers (e.g., fingerprints) '
xix. Full face photo images
xx. Unique identifying numbers

WHAT ABOUT STATE & LOCAL LAWS?

Applicable State and Local Laws

The HHS regulations do not affect any applicable State or local laws or regulations which provide additional protections for human subjects [see 45 CFR 46.101(f)].

State Laws

Because Dallas Theological Seminary's campuses and students are located in various states throughout the United States, it is the responsibility of the principal investigator to be familiar with and adhere to all state laws within the research jurisdiction. It is the principal investigator's responsibility to provide the IRB with information about application state regulations.

Local Laws

Researchers are expected to know and abide by any local or municipal laws when conducting research. Researchers working in jurisdictions off campus are responsible for obtaining this information. This is also true for research conducted in other countries. It is the principal investigator's responsibility to provide the IRB with information about local regulations.

WHAT IRB TRAINING IS REQUIRED?

The Collaborative Institutional Training Initiative (CITI) or the National Institute of Health's training on Protecting Human Research Participants

- All IRB committee members must maintain CITI and/or NIH certification. Before submitting an IRB application, all research personnel are required to take the appropriate CITI/ NIH training modules and attach complete certificates for all study personnel to their IRB application.
- Training expires after a three year period. It is the principal investigator's responsibility to ensure that all research personnel have updated certifications filed with the IRB.
- Failure to maintain certification is treated as an adverse event.

WHAT ARE THE CATEGORIES O F REVIEW?

Exempt Review

- The federal government has identified certain categories of research involving human subjects that qualify for exemption from federal regulations. At Dallas Theological Seminary, determinations of exemption are made by the IRB (not by the principal investigator). In order to make this determination, the IRB uses 45 CFR 46.101(b) and must include documentation regarding the specific category justifying the exemption in its notification to the principal investigator. When the IRB notifies a principal investigator that a research project is exempt, it also notifies the principal investigator that the research is approved for initiation or continuation.

- In order to qualify for exemption, a research study must fall entirely within one or more of the six categories for exemption outlined by HHS and it cannot place subjects at greater than minimal risk. Exemption means that a research protocol is exempt from the requirements set forth in 45 CFR 46.101b. Exemption does not mean that the protocol is exempt from local and/or state laws. 11 Publicly available unidentified data (such as CDC data) is considered exempt from IRB under 45 CFR 46.101(b).

Expedited Review

- Expedited review is a procedure through which certain kinds of research may be reviewed and approved without convening a meeting of the full IRB. A list of categories of research has been established by HHS that may be reviewed by the IRB through an expedited review procedure.

- In order to qualify for expedited status, reviewer(s) must find the protocol to involve no more than minimal risk. For ongoing projects, minor changes in previously approved research during the period (of one year or less) for which approval is authorized may qualify for expedited status. At Dallas Theological Seminary, determinations of exemption are made by the IRB (not by the principal investigator). Examples of minimal risk procedures include EKGs, moderate exercise testing, and administration of psychological tests involving a minor level of stress. Archived data from a previous research study may require expedited review.

Full Review

- If the study does not meet the criteria for exempt or expedited review, then it must undergo full IRB review. Activities that require full review are those that require more advanced medical procedures, such as blood draws, and those that involve specific populations of protected individuals, such as children, pregnant women, prisoners, or current students/ subordinates of the researcher.

WHAT IS THE IRB COMMITTEE?

As a group, the IRB committee is responsible for:

i. Ensuring rights, safety, and welfare of human research subjects;
ii. Ensuring compliance with all application federal and state laws/regulations;
iii. Conducting ethical review of human subject research activities including initial, continuation, medication, unanticipated problems, and alleged noncompliance;
iv. Applying disciplinary and regulatory knowledge;
v. Disclose conflicts of interest;
vi. Complete mandatory education requirements;
vii. Maintain confidentiality.

WHAT IS A PRINCIPAL INVESTIGATOR?

Principal Investigator Responsibilities

- The principal investigator must request IRB approval for any research project involving human participants regardless of sample size. The principal investigator is responsible for designing and implementing his/her research in such a way as to minimize the risk of potential harm to participants and to have a plan in place to ameliorate any adverse consequences that participants may experience.

- The principal investigator will not collect any data until an approval by the IRB of their project is received. The principal investigator will ensure that procedures for the protection of human subjects are followed as described in their approved application and required by policy and federal law.

WHAT IS DOCUMENTATION IS REQUIRED?

i. Documentation Principal investigators will be responsible for submitting all required documents prior to review. Detailed information on the required documents can be found on the Office of Institutional Research & Effectiveness IRB Webpage or via the IRB Director. The required documentation includes:

   - 1. The completed application
   - 2. The entire research proposal
   - 3. Instrumentation (e.g., surveys, participant recruitment information)
   - 4. Informed consent and assent forms
   - 5. Cover letter to participants
   - 6. External letters of approval from partnering institutions (e.g., IRBs)
   - 7. Additional materials (as required)

WHAT ABOUT TRAINING REQUIREMENTS?

- The principal investigator (and all other signatories on the application [faculty sponsor, co-investigators, and students research assistants, etc]) must complete **CITI/ NIH and HIPAA** (when necessary) training and submit copies of certification of these trainings with their IRB application.

- CITI/NIH and HIPAA training certification is **valid for a period of three years** and must be renewed prior to expiration while research is continuing or if significant policy changes occur.

WHAT ARE "PI" ETHICAL CONSIDERATIONS?

The principal investigator is also responsible for:

1. Ethically conducting research with each human subject;

2. Designing and implementing ethical research without sound study designs according to The Belmont Report;

3. Involving research personnel qualified by training and experience for their research responsibilities;

4. Obtaining IRB approval prior to initiating human research activity;

5. Complying with federal and state regulations, institutional and IRB requirements, and requirements of HIPAA;

WHAT IF MY STUDY CHANGES?

Changes to Protocol

- The IRB must be informed of any changes which might influence the completion of an approved research study. A Notification Form (NF) must be submitted to the IRB when there is a change to the original proposal which can influence the collection of data and treatment of subjects. The NF must be submitted to the IRB prior to implementation of the changes. Events that require IRB notification and approval include (yet are not limited to):
  - An unexpected interruption of the research study process
  - Research protocol changes/adjustments (e.g., methodology, recruitment, etc.) • Instrumentation changes/adjustments (e.g., existing or new)
  - A change in the demographics of research participants recruited
  - Inclusion of additional research participants

WHAT ABOUT UNANTICIPATED PROBLEMS?

IRB Review of Adverse Events

- The IRB will review the **unanticipated problem/event report(s) and determine whether the report represents an unanticipated problem/event involving risks to subjects** or others based on whether the problem is unanticipated and indicates that subjects or others are at increased risk. If not, or if the problem is determined by the reviewer to involve minimal risk to subjects or others, no further action is taken under this policy. If it does represent an unanticipated problem/event involving more than minimal risks to subjects or others, the IRB will implement a corrective action. These actions include, but are not limited to:

- a. changes to the protocol initiated by the investigator prior to obtaining IRB approval to eliminate apparent immediate hazards to subjects may need to be made a permanent part of the protocol
- b. modification of inclusion/exclusion criteria to mitigate the newly identified risks
- c. implementation of additional procedures for monitoring subjects, the consent process and/or the research
- d. suspension of enrollment of new subjects
- e. suspension of research procedures on currently-enrolled subjects
- f. modification of the protocol

WHAT IS VOLUNTARY PARTICIPATION?

Voluntary participation and informed consent are at the very core of the need for IRB oversight.

- How that consent is achieved varies based on the research design and the level of review. Informed consent is a process, not just a form. Information must be presented to enable people to voluntarily decide whether or not to participate as research subjects.
- It ensures respect for people by providing the opportunity for thoughtful consent to ensure that participation is voluntary.
- The procedures used to obtain informed consent should be designed to educate the subject population in terms that they can understand to ensure that research participants understand the consent they have provided.
- All research requires informed consent.

WHAT IS INFORMED CONSENT

As a result, the IRB will seek to ensure that the following general requirements of informed consent are satisfied in all studies:

a. Informed consent must be prospectively obtained from the participants or their legally authorized representatives;

b. Information must be conveyed in **understandable language**, which may necessitate that the form be translated (and reverse translated as a check for accuracy);

c. Subjects must be given **sufficient opportunity to consider** whether they want to participate;

d. Consent must be given **without coercion** or undue influence; and

WHAT IS ASSENT FOR CHILDREN?

Assent

-Minor children (under age 18) should be given an explanation - at a level appropriate to the child's age, maturity, experience, and condition

- Clearly explain the procedures to be used for recruiting participants,

-their meaning to the child in terms of discomfort and inconvenience,
and the general purpose of the research.

Children should be asked if they wish to participate in the research or not. Mere failure to object on the part of the child should not, in the absence of affirmative agreement, be construed as assent.

WHEN IS WRITTEN CONSENT NOT REQUIRED?

Waiving one or more requirements of informed consent Based on CFR 46.116, the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

a. The research or demonstration project is to be conducted by or subject to **the approval of state or local government officials** and is designed to study, evaluate, or otherwise examine: public benefit or service programs;

b. The research involves no more than **minimal risk** to the subjects;

c. The waiver or alteration will **not adversely affect the rights** and welfare of the subjects;

d. The research could **not practicably be carried out** without the waiver or alteration; and

e. Whenever appropriate, the subjects will be provided with additional pertinent **information after participation**.

f. The research is **not FDA regulated**. It is the IRB's discretion whether a waiver of one or more requirements of consent may be allowed. If consent documentation is waived, the principal investigator will be notified in writing and the reason for allowing the waiver will be expressly stated.

WHAT ABOUT DOCUMENTATION OF CONSENT?

- All consent documents must be submitted for IRB review and must be approved before use. Based on OHRP's recommendation, Dallas Theological Seminary requires that all approved consent documents be stamped with approval and expiration dates and stipulates that copies of these dated documents must be used in obtaining consent.

- This procedure helps ensure that only the current, IRB-approved informed consent documents are presented to subjects and serves as a reminder to the investigators of the need for continuing review.

WHAT ABOUT POTENTIAL RISKS?

- The IRB identifies and analyzes potential sources of risk and measures to minimize risk, including physical, psychological, social, legal, or economic risks. The IRB will evaluate the principle investigator's submission to determine the following:
- • Risks to participants are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk.
- • Risks to participants are minimized, when appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
- • Risks to participants are reasonable in relationship to the potential benefits, if any, to participants, and the importance of the knowledge that may be expected to result from the research.
- • The IRB should consider risks and benefits that may result directly from the research. • The IRB also considers a wide range of benefits, including therapeutic, educational, informational, or broad empowerment benefits using the appropriate review guide checklists applicable to the type of research (DHHS, FDA, VA). Benefits may accrue to the participants or their community.

WHAT ARE THE TYPES OF RISKS FOR HUMAN SUBJECTS?

- 1. Physical Harm Medical research often involves exposure to minor pain, discomfort, or injury from invasive medical procedures, or harm from possible side effects of drugs. All of these should be considered "risks" for purposes of IRB review. Some of the adverse effects that result from medical procedures or drugs can be permanent, but most are transient. Procedures commonly used in medical research usually result in no more than minor discomfort (e.g., temporary dizziness, the pain associated with venipuncture).
- Some medical research is designed only to measure more carefully the effects of therapeutic or diagnostic procedures applied in the course of caring for an illness. Such research may not entail any significant risks beyond those presented by medically indicated interventions. On the other hand, research designed to evaluate new drugs or procedures may present more than minimal risk, and, on occasion, can cause serious or disabling injuries.
- 2.Psychological Harm Participation in research may result in undesired changes in thought processes and emotion (e.g., episodes of depression, confusion, or hallucination resulting from drugs, feelings of stress, guilt, and loss of self-esteem). These changes may be transitory, recurrent, or permanent. Most psychological risks are minimal or transitory, but some research has the potential for causing serious psychological harm.
- Stress and feelings of guilt or embarrassment may arise simply from thinking or talking about one's own behavior or attitudes on sensitive topics such as drug use, sexual preferences, selfishness, and violence. These feelings may be aroused when the subject is being interviewed or filling out a questionnaire. Stress may also be induced when the researchers manipulate the subjects' environment - as when "emergencies" or fake "assaults" are staged to observe how passersby respond. More frequently, however, is the possibility of psychological harm when behavioral research involves an element of deception.

WHAT ARE WAYS WE CAN MINIMIZE RISK?

Ways to Minimize Risk

i. Principal investigators should:

   i. Provide complete information in the protocol regarding the experimental design and the scientific rationale underlying the proposed research, including the results of previous animal and human studies.

   ii. Ensure that the projected sample size is sufficient to yield useful results.

   iii. Incorporate adequate safeguards into the research design such as an appropriate data safety monitoring plan, the presence of trained personnel who can respond to emergencies, and procedures to protect the confidentiality of the data (e.g., encryption, codes, and passwords).

WHAT ABOUT PARTICIPANT BENEFITS?

Study participants may (but not necessarily) be compensated monetarily or provided other incentives or inducements as symbolic recognition for their enrollment and/or continuing contributions to research. When given, such compensation, incentives or other inducements must be limited in extent and manner so they are not perceived to be coercive or providing undue influence or duress; and they should be provided without regard to a subject's economic status.

Incentives, compensation and/or other inducements to subjects should reflect the risk, discomfort or inconvenience associated with study participation; and they should not be so large as to result in any one group of individuals (such as the economically disadvantaged) bearing an unduly large share of the risks and burdens of research participation.

Incentives, compensation or inducements must not be such that a subject's participation in research is other than voluntary. IRB study approval requires that the promise or expectation of a reward for study participation should not influence a subject's willingness to participate in the research. Nor should rewards influence a subject's decision-making process such that the subject acts without due consideration of the risks of participation.

In IRB deliberations, incentives/compensation or other inducements must not be considered a "benefit" off-setting (in whole or part) "risk" to subjects. Rather, the IRB must be assured that these are not influencing subjects to participate in research that they would not otherwise choose to participate in.

WHAT ABOUT THE RISK/BENEFIT ASSESSMENT?

Risks to subjects who participate in research should be justified by the anticipated benefits to the subject or society. This requirement is found in all codes of research ethics, and is a central requirement in the Federal regulations (45 CFR 46.111 and 21 CFR 56.111). Two of the required criteria for granting IRB approval of the research are:
a. Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
b. 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 Committee will 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 is responsible for evaluating the potential risks and weighing the probability of the risk occurring and the magnitude of harm that may result. It must then judge whether the anticipated benefit, either of new knowledge or of improved health for the research subjects, justifies inviting any person to undertake the risks. The IRB cannot approve research in which the risks are judged unreasonable in relation to the anticipated benefits. The IRB must:

a. Identify the risks associated with the research, as distinguished from the risks of therapies the subjects would receive even if not participating in research;
b. Determine that the risks will be minimized to the extent possible;
c. Identify the probable benefits to be derived from the research;
d. Determine that the risks are reasonable in relation to be benefits to subjects, if any, and the importance of the knowledge to be gained; and
e. Assure that potential subjects will be provided with an accurate and fair description (during consent) of the risks or discomforts and the anticipated benefits.

The benefits of a study do not alter the risk classification. The risk/benefit assessment only refers to the acceptability of the risk, not the level of the risk. A study deemed greater than minimal risk cannot be classified as minimal risk because the potential benefits are great, but it could be approved for this reason. Whereas, the same greater than minimal risk study may not be approvable if the benefits are lacking. An IRB reviewer should disapprove research in which the risks are judged to be unreasonable in relation to the anticipated benefits.

WHAT ABOUT SELECTION OF SUBJECTS?

IRBs are required to make a specific determination that the selection of subjects is equitable. As a matter of social justice, there should be an order of preference in the selection of classes of subjects: adults before children, competent individuals before incompetent individuals, and noninstitutionalized persons before institutionalized persons. In addition, those who are already burdened (e.g., by disabilities or institutionalization) should not be asked to accept the burdens of research unless other appropriate subjects cannot be found (i.e., if the research concerns their particular disability or circumstance). IRBs should consider the extent to which a proposed subject population is already burdened by poverty, illness, poor education, or chronic disabilities in deciding whether they are a suitable subject population.

5. Vulnerable populations

i. Residents of any facility Prisoners and patients in mental institutions are confined under the strict control of people whom they must please and to whom they must appear cooperative and rational if they are to earn their release. These potential subjects may believe, probably as a result of their dependent situation, which agreeing to participate in research will be viewed positively by their wardens, psychiatrists, or social workers. They are also readily available in large numbers, and, therefore, have historically been involved as subjects of drug research that is totally unrelated to the basis of their confinement. Mental patients and prisoners have accepted the risks of research in disproportionate numbers, while the benefits of the research in which they participated went to all segments of the population. Investigators are required to justify any proposed involvement of hospital patients, other institutionalized persons, disproportionate numbers of racial or ethnic minorities, or persons at the lower end of the socioeconomic scale.

1. Prisoners

In addition to the requirements of subparts A and C of 45 CFR 46, additional requirements pertain to research involving prisoners. In summary, the major additional considerations are: the exemptions that generally apply to certain types of research involving human subjects do not apply to research involving prisoners (45 CFR 46.101, footnote 1); in order to approve research involving prisoners, the IRB must find that the proposed research falls into one of the permissible categories of research; the institution must certify to OHRP that an IRB has reviewed the proposal and made seven required findings, and receive OHRP authorization prior to initiating any research involving prisoners (45 CFR 46.305c); the IRB must include a prisoner or prisoner representative (or approval from their system IRB) (45 CFR 46.304b) and meet a membership requirement concerning the number of IRB members not associated with a prison involved in the research(45 CFR 46.304a); and 34 waiver of informed consent in emergency research is not applicable to research involving prisoners (61 FR 51531).

WHAT ARE POTENTIAL RISKS FOR SUBJECTS WHO ARE PREGNANT WOMEN, MINORITIES OR CHILDREN?

The research should include minorities and women in study populations so that the research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study. If a proposed project includes a study population in which women and minorities are not appropriately represented, the investigator must provide a clear compelling rationale for their exclusion or inadequate representation."

1. Pregnant women

Pregnant women may be involved in several categories of research. The primary objectives are assessing: (1) whether the research is directed toward the mother's health or toward the fetus; and (2) the risks to the woman and to the fetus or infant. Subsequent actions depend on those assessments. For research activities directed toward pregnant women as subjects, the federal regulations provide that no pregnant woman may be involved as a subject unless either: (1) the purpose of the activity is to meet the health needs of the mother, and the fetus will be placed at risk only to the minimum extent necessary to meet such needs; or (2) the risk to the fetus is minimal [45 CFR 46.207].

iii. Children and minors

The special vulnerability of children makes consideration of involving them as research subjects particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations are in place for reviewing research involving children. Title 45 CFR Part 46, Subpart D provides for "Additional Protections for Children Involved as Subjects of Research." Research that is contrary to the rights and welfare of child-subjects is prohibited.

IRBs reviewing research involving children as subjects must consider the benefits, risks, and discomforts inherent in the proposed research and assess their justification in light of the expected benefits to the child-subject or to society as a whole. In all cases, the IRB must determine that adequate provisions have been made for soliciting the assent of children and the permission of their parents or guardians [45 CFR 46.408].

1. *Consent procedures*

When children or minors are involved in research, the regulations require the assent of the child or minor and the permission of the parent(s), in place of the consent of the subjects.

WHAT ARE POTENTIAL RISKS FOR SUBJECTS WHO ARE STUDENTS OF THE RESEARCHER?

1. Students as Researchers

i. Students conducting class projects, dissertations, and theses. Research conducted by students of DTS as part of their academic requirements is subject to review by the IRB. Research in this case is defined as any interaction to collect data that is not part of an informal interview (up to 3 of these are allowable) on a non-sensitive subject with someone who is not part of a vulnerable population and for which the data will not be used outside of the current class and no personally identifying information is recorded. Students should consult with the assigned faculty member for the class and/or the chair of their thesis/dissertation committee for guidance on what activities are exempt from IRB review.

2. Students as research subjects

Principal investigators who wish to recruit students from DTS as participants in their research must receive approval from the DTS IRB, regardless of the affiliation of the principal investigator with Dallas Theological Seminary or lack thereof. It is the principal investigator's responsibility to recruit subjects as the Dallas Theological Seminary IRB will not provide student directory contact information to principal investigators. Principal investigators must incorporate compliance with applicable FERPA guidelines in their research design and IRB application.

3. Investigator and IRB member conflicts of interest

A member of the IRB may not certify compliance of a research proposal for which the IRB member has a direct interest either as a principal investigator or co-investigator OR as a committee member or a faculty sponsor of a student's research project. When an IRB committee member has provided scientific guidance on a project or has some other relationship with the investigator (i.e. supervisee), he/she may still review the application as long as the extent of said guidance is minimal (for instance, helping someone identify an appropriate statistical measure is "minimal," while helping someone submit a grant is not).

iii. Students of the researcher

Researchers who include students as research subjects must be able to provide a rationale other than convenience for selecting them and must show that the recruitment method does not lead students to think they will be compromised by not participating. The compromised circumstances and fear of retribution, even subtle cues of compromise, can place students in a position of involuntary participation in a research project.

Whenever possible, researchers should avoid using their own students if another population of subjects is equally suited to the research question (e.g., another class section not taught by the researcher, recruitment by another instructor, or blinded/coded data collected by an associate) so that subjects are not identified to the instructor.

WHAT ARE POTENTIAL RISKS FOR SUBJECTS WHO ARE NOT FLUENT IN ENGLISH?

All translations of documents must be certified by a qualified translator who is acceptable to the IRB (an “Acceptable Translator”). The IRB will use its discretion in determining whether the credentials of the translator are acceptable, based on the nature and level of risk involved in the research study.

For each translation described in items 1 and 2 below, the IRB must receive a letter or other written documentation certifying that the translation is consistent in content, style, and level of readability with the IRB-approved document and, for non-commercial translators, an explanation of the translator’s qualifications. The letter or other documentation should reference the IRB approval and expiration dates of the study, as well as a document identifier (i.e., consent form number, document title) that is unique to each IRB-approved item that is being translated.

Acceptable translators include the following, although all may not be appropriate for all types of research:

- A commercial entity that provides translations as a service to the public.
- An individual who is bilingual and fluent in both English and the language of the Non-English Speaking Subject, for minimal risk studies.

For research that is greater than minimal risk, the translated document must be back-translated into English by another individual who is also bilingual and fluent in both languages; for Spanish translations, item 5 below may be utilized in lieu of the back translation. If the research is a minor increment over minimal risk, the IRB may waive the requirement of the back translation into English.

WHAT ARE POTENTIAL RISKS SUBJECTS WHO ARE INDIVIDUALS IN CRISIS?

Individuals who are in crisis

A humanitarian crisis does not allow for the suspension of the ethical foundations governing human subject's research. A disaster such as an earthquake has the potential to leave overwhelming numbers of people homeless and financially devastated—the very definition of a vulnerable group. Federal regulations outline more—not fewer—research protections for such vulnerable populations (45 CFR sec 46. 2009 ed.). The vulnerable status of the proposed subjects makes IRB review even more critical.

Economically disadvantaged individuals

Economically disadvantaged individuals may be particularly vulnerable to the risks of research. They may be easily persuaded to participate in research if the economic compensation is so great that it would result in the subject ignoring or disregarding the research risks because of the income generated by the study. In such cases investigators should be careful to set economic compensation at a meaningful level that compensates the subject for her/his time, but it not so great that it becomes coercive. It is also important in such cases that the risks to the subjects be made clear to the subjects.

WHAT ARE POTENTIAL RISKS FOR SUBJECTS WHO ARE ELDERLY?

Elderly subjects

Elderly subjects are persons over the age of 65. Advancing age may place them at increased physical, cognitive, or financial risks. However, there is no specific age at which persons become high risk subjects and thereby ineligible for research. Researchers have the responsibility to determine the level of risk that research poses on an individual basis and to minimize risks accordingly.

The use of age per se to define the ability to consent and therefore to participate in research is not valid, and the inclusion of older persons in the research enterprise is important. When older persons are cognitively impaired or institutionalized, the same protections apply to them that apply to persons with cognitive or emotional impairments and to children. They should not be used as subjects merely because they provide a convenient sample, but research involving elderly institutionalized persons should bear some direct relationship to their condition or circumstances. Furthermore, they should be informed and given the opportunity to assent to research, to the extent they are able, even if a guardian must provide informed consent for them to be subjects.

Researchers should be aware that merely because an elderly individual agrees to participate in research, that this does not necessarily guarantee that the decision was truly voluntary. A debilitating illness associated with aging can make a potential subject susceptible to being manipulated. Further, a potential subject might enroll in a protocol out of desperation because he or she may believe that no other treatment option is available. Researchers must be cautious not to take advantage of this desperation in order to promote their own agenda, and they must inform potential participants regarding existing treatment options for their condition.

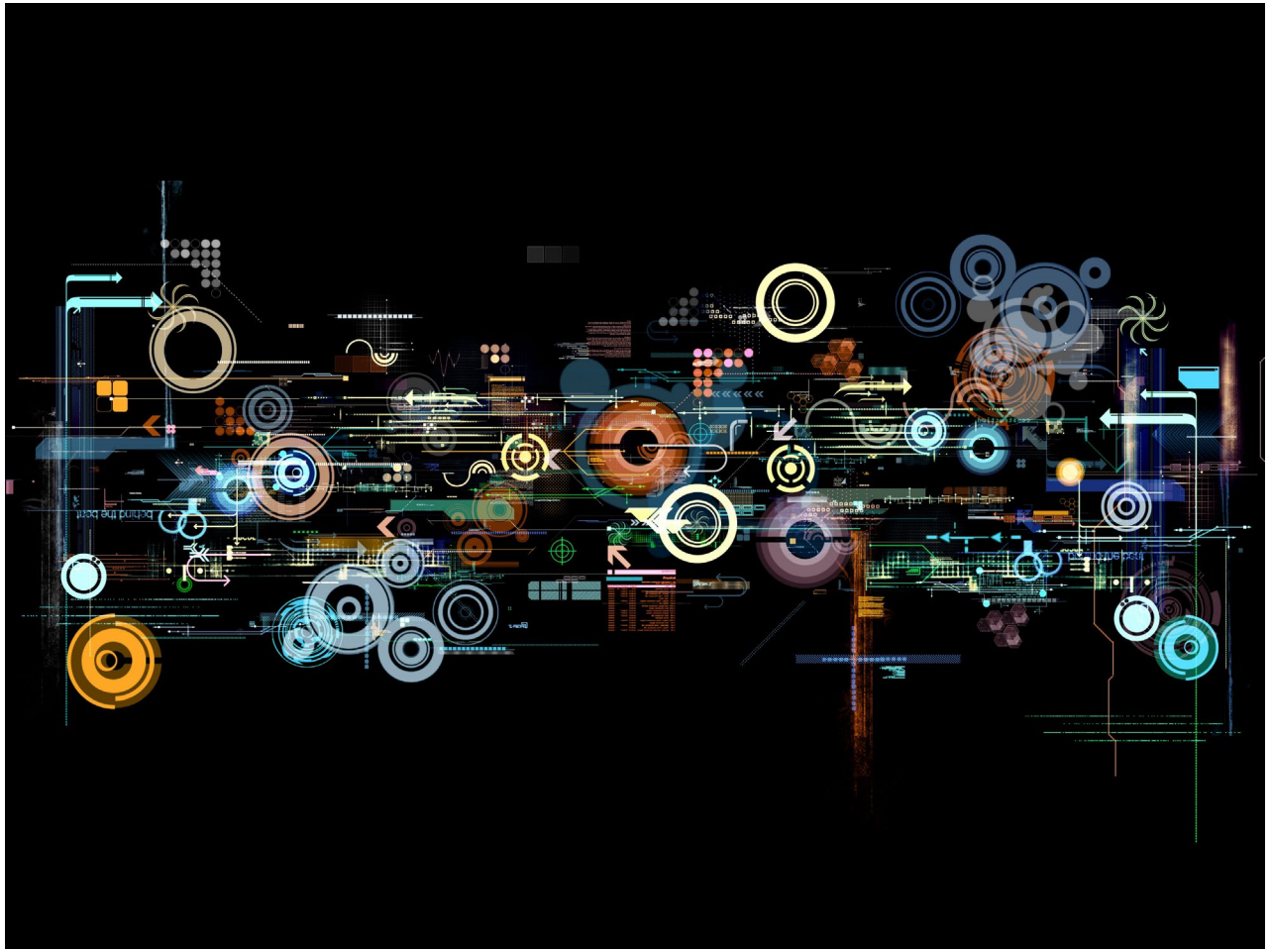
NON-COMPLIANCE WITH IRB POLICIES?

The Office of Institutional Research & Effectiveness IRB serves the role of ensuring all research studies meet the necessary policies and procedures of the University and those of the Department of Health and Human Services, regarding the Protection of Human Participants. The IRB remains committed to assisting the research endeavors of investigators involved with Dallas Theological Seminary. As such, all policies and procedures associated with conducting and reporting research require strict adherence, with no exceptions. All investigators and research personnel must ensure awareness and understanding of the explicit and implicit rules and policies.

1. Notification to Cease Research Activities (NCRA)

   In the event that an investigator(s) or associated research personnel fail to comply with the rules and policies, a formal Notification to Cease Research Activities (NCRA) may be issues by the IRB Chair. In such event, all research activities (e.g. participant recruitment/advertisement, research procedures including instrumentation and methodology, etc.) must cease. Once an NCRA has been issued, a meeting between the investigator(s) and representatives from the IRB committee will be scheduled to discuss the issues and needed course of action. Once an NCRA has been issued, activities for the project can be resumed upon receipt of a formal Notification to Resume Research Activities (NRRA).

   Failure to follow the guidelines of the NCRA will result in withdrawal of the approval for the project and the investigators will need to resubmit the entire application. Additional sanctions and/or disciplinary action may also result (see chart).



WHAT ABOUT COOPERATIVE RESEARCH?

Cooperative Research
Cooperative research is any research that is conducted at a site not covered by the Office of Institutional Research & Effectiveness IRB's authority.

There will be times when DTS faculty will collaborate or work with individuals from other universities, which may require submission to other IRBs. Any faculty participating in research must have the project reviewed by the Dallas Theological Seminary IRB.

Research sites may require their own IRB review or may wish to create a relationship with Dallas Theological Seminary to accept the IRB review, without further review or action. In the event of cooperative research, authorization agreements are necessary from both sites and must be submitted to the acting IRB.

WHAT ABOUT RESEARCH SITES WITH AN IRB?

Research Sites with an IRB

If the other institution has an IRB and wishes to provide the review, DTS can accept their review under the following circumstances:

a. The Reviewing IRB shall ensure that Dallas Theological Seminary's IRB's organization has agreed to rely on the Reviewing IRB for the specific study. The IRB at any institution has the right to decline, on a case by case basis, to be the Reviewing IRB for research being conducted at other institutions.

b. The Reviewing IRB will consider conflicts of interest using its local Conflict of Interest policy. The Reviewing IRB will include the Conflict of Interest management plan applicable to investigators from relying organizations in the study approval.

c. The Reviewing IRB will notify the DTS IRB of any unanticipated problems involving risks, serious or continuing non-compliance with regulations or requirements or determinations of the Reviewing IRB, and termination or suspension of IRB approval of research. The Reviewing IRB will collaborate with Relying IRBs in drafting joint notification on such subjects to any required reporting agencies.

d. The Reviewing IRB will make its records, including any relevant communications with investigators, available upon request to the DTS IRB and to regulatory and accrediting organizations.

e. The Reviewing IRB will communicate to the DTS IRB, all approvals, disapprovals and/or closures of the proposed research.

f. The Reviewing IRB may require the DTS IRB to conduct a monitoring visit of the study and/or observe the consent process at the relying institution.

g. The Reviewing IRB has the right to terminate serving as the IRB of record, after initial approval of a study. The Reviewing IRB may terminate serving as the IRB of record with at least six months advance written notice to the Principal Investigator and the DTS IRB, in order to provide time for the protocol to be transferred to another IRB.

h. The principal investigator, not the Office of Institutional Research IRB, is responsible for subject recruitment. It is unacceptable to use the faculty or staff directory to send emails to faculty members or staff for subject recruitments purposes.

WHAT ABOUT INTERNET RESEARCH?

Internet Research

Internet research involves the transmission of participant information and response via online sources, such as Survey Monkey.

All research conducted through the internet rather than face to face formats must adhere to all policies of the IRB, including informed consent and proposal review.

See informed consent procedures for online research. See the Dallas Theological Seminary IRB Webpage or contact the IRB Director for sample informed consent guidelines.

WHAT ABOUT IRB AND GRANTS?

The DTS IRB grants the Reviewing IRB the authority to:

a. Approve, require modifications to secure approval, disapprove; and to suspend, or terminate the research when not being conducted in accordance to the Reviewing IRB's requirements or has been associated with unexpected serious harm to subjects.

b. Observe, or have a third party observe, the consent process and the conduct of research. The Office of Institutional Research IRB will notify the Reviewing IRB of any significant or serious issues relating to the conduct of the study at its site. Examples of such issues include, but are not limited to, noncompliance by an investigator on another study or a serious adverse event.

The IRB Director, or that of his designee, will review all correspondence and protocol specific communications received by the Reviewing IRB or site's principal investigator pertaining to all research being conducted at DTS, under the approval of another IRB.

The DTS Institutional Officer may suspend or terminate the conduct of research at any of its components. In the case of such an occurrence, the DTS IRB will promptly notify the Reviewing IRB in writing. The Office of Institutional Research & Effectiveness IRB may terminate, on a case by case basis, its reliance on the Reviewing IRB.

The DTS IRB will notify the site's principal investigator and the Reviewing IRB and ensure that the research has been reviewed and approved by another IRB prior to termination of reliance.

WHAT ABOUT RESEARCH SITES WITHOUT AN IRB?

1. Research Sites without an IRB

   In the event that a cooperative research site does not have an IRB, the DTS IRB will serve as acting IRB. Any site utilized for research for DTS must be included in the IRB proposal reviewed by the Office of Institutional Research & Effectiveness. All research conducted by DTS faculty must have IRB review and approval.

   Note that while research conducted at a DTS site (whether physical or electronic) does not need site approval (for instance from campus administration), investigators should notify supervisors or an administrator before commencing data collection.

WHAT ABOUT INTERNATIONAL RESEARCH?

International Research

When performing human subject research in foreign countries, Office of Institutional Research & Effectiveness expects that the research activities are consistent with the ethical principles set forth in the IRB Policy and Procedure manual and provide levels of subject protection equivalent to those provided when performing human subject research in the United States. Researchers are also expected to comply with local laws and take into account the cultural context of the country in which the research is taking place.

When performing human subject research in other countries, researchers are expected to comply with U.S. regulations and guidelines and any applicable regulations of the country in which the research is performed. Specifically, the investigator(s) agree to:

i. Provide the same or equivalent protections to human subjects in research conducted in other countries,
ii. Respect subject autonomy and dignity,
iii. All protections should encompass the ethical principles of respect for person, beneficence, and justice.

Researchers agree to be aware of and abide by local laws, regulations, political and socioeconomic factors, and cultural context in all locations where the research is conducted. In addition, the researcher is expected to:

i. have sufficient knowledge of the local context to enable carrying out of the research in ways that protect the rights and welfare of subjects,
ii. Have knowledge of the local context may influence all aspects of the research design,
iii. Comply with local laws and adhere to cultural norms.

Requirements and expectations for reviewing proposed international research includes specific guidelines. Generally:

i. The IRB must ensure that equivalent protections are provided to research subjects enrolled in research in another country
ii. The IRB will make determinations and decisions based on laws and knowledge of the country in which the research will be conducted, including if there are laws or guidance related to human research subject protections if there are other laws that will need to be factored into the research, and if the local or government has their own required approvals.

Reviewers should review the HHS International Compilation of Human Subject Protections found at http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html for more information on making these determinations.

WHAT SPECIFIC INFORMATION SHOULD BE INCLUDED IN THE IRB PROPOSAL?

- Specific information to be included in the IRB proposal

i. The IRB will require certain information be addressed in the submitted protocol. For example, the information provided should include but not be limited to:

ii. Whether the researcher speaks the language of the country in which participants will be enrolled and the research will be conducted. If the researcher does not speak the local language, describe how communication with the research subjects will be accomplished.

iii. Whether the researcher is familiar with the local customs and culture or whether a local collaborator will be used and the involvement of the local collaborator will have in the conduct of the research.

iv. Whether the subjects will be reimbursed and, if reimbursed, the amount and how it relates to the local economy and subject income.

v. If consent will be obtained, how or from whom will consent be obtained along with the following information, if applicable:

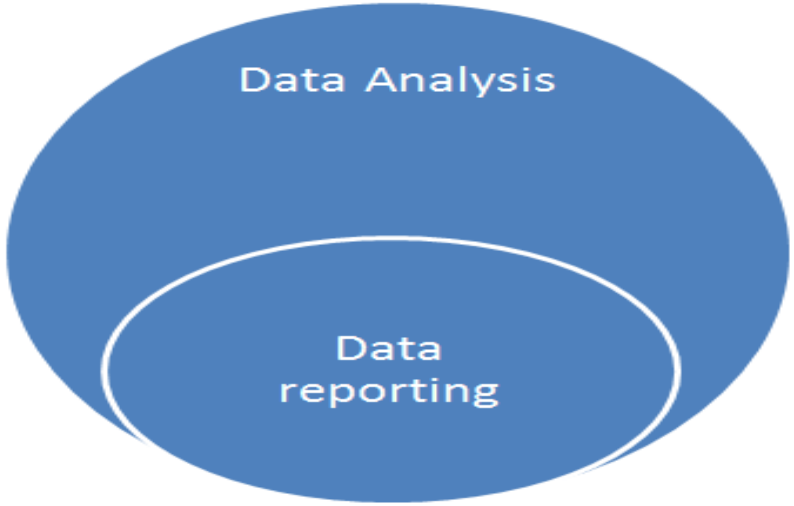
a. Describe local customs/culture in which the subject might not have the autonomy to provide consent and a family member or other person will be providing consent to participate.

b. How the researcher will assure that there is no coercion for participation if a person other than the subject will be providing consent.

c. If written documentation of consent will be obtained, and If so, a description of how or from whom the consent will be translated.

d. If not, a description of how consent will be documented or if there are cultural/other prohibitions regarding use of consent forms.

v



WHAT ABOUT RISK ASSESSMENT AT FOREIGN SITES?

Risk Assessment

The Office of Institutional Research & Effectiveness IRB must assure that the risk assessment is accurate for the foreign site. Research methods that have minimal risk in the U.S. might have greater than minimal risk when conducted at certain foreign sites. The following must be given consideration:

i. Questions that might be innocuous in the U.S. could be offensive at certain foreign sites.

ii. Assuring and maintaining confidentiality may be difficult in other countries.

iii. Breach of confidentiality in the research locale could have dangerous consequences.

WHAT ABOUT CONFIDENTIALITY FOR INTERNAL SUBJECTS AT FOREIGN SITES?

Describe how the privacy for the subjects and confidentiality of their research data will be assured and if there is a local custom that research data be revealed to someone other than the subject.

Describe how the communications with the DTS IRB/local authorities will be achieved for requesting amendments or reporting unanticipated problems.

For student researchers, a description how the academic faculty sponsor(s) will oversee conduct of the research.

The investigator (s) will provide the Office of Institutional Research & Effectiveness IRB requires the applicable local laws and regulations for the country where the proposed study will occur. The principal investigator shall provide the IRB with any necessary certifications or permissions and evidence of local ethics review when appropriate.

To help ensure compliance with this requirement the IRB committee will utilize the U.S. Department of Health & Human Services International Compilation of Human Subject Protections found at http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html and may utilize a consultant with knowledge of the laws and practices of the country.

WHAT ABOUT SPECIAL CONSIDERATION FOR INFORMED CONSENT DURING INTERNATIONAL RESEARCH ?

Special Considerations for the Informed Consent

i. The informed consent process must honor local custom. Some cultures may have a different authority structure for consent.

ii. The local consent structure may seem coercive and clash with the researcher's, reviewer's, or IRB's views on autonomy.

iii. Surrogate consent/permission should not substitute for a subject's informed consent unless the IRB has approved an alteration or waiver to the consent process.

iv. The consent process/form should, unless waived by the IRB, contain all required elements of informed consent.

v. Consent is best obtained using the language that is most familiar to the subjects taking into account:

a. Some languages/dialects are not written.
b. Subjects may be illiterate/unable to read.
c. There may be words in the foreign language that do not translate to/from English. d. If researchers are not fluent in the local language, interpreters/translators who are fluent should be used.

vi. Documentation of consent may be difficult because: a. In some cultures, it may be inappropriate to ask for a signature b. There may be legal implications when signing documents. c. Subjects may be suspicious, distrustful, or fearful they are giving up their rights when asked to sign documents.

vii. Alternate consent procedures may have to be considered such as: a. Use of pictures, video, or computers. b. Alternate forms of documentation such as thumbprints

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- Specific information to be included in the IRB proposal

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iii. Whether the researcher is familiar with the local customs and culture or whether a local collaborator will be used and the involvement of the local collaborator will have in the conduct of the research.

iv. Whether the subjects will be reimbursed and, if reimbursed, the amount and how it relates to the local economy and subject income.

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a. Describe local customs/culture in which the subject might not have the autonomy to provide consent and a family member or other person will be providing consent to participate.

b. How the researcher will assure that there is no coercion for participation if a person other than the subject will be providing consent.

c. If written documentation of consent will be obtained, and If so, a description of how or from whom the consent will be translated.

d. If not, a description of how consent will be documented or if there are cultural/other prohibitions regarding use of consent forms.

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Describe how the privacy for the subjects and confidentiality of their research data will be assured and if there is a local custom that research data be revealed to someone other than the subject.

vii. Describe how the communications with the DTS IRB/local authorities will be achieved for requesting amendments or reporting unanticipated problems.

viii. For student researchers, a description how the academic faculty sponsor(s) will oversee conduct of the research.

ix. The investigator (s) will provide the Office of Institutional Research & Effectiveness IRB requires the applicable local laws and regulations for the country where the proposed study will occur. The principal investigator shall provide the IRB with any necessary certifications or permissions and evidence of local ethics review when appropriate. To help ensure compliance with this requirement the IRB committee will utilize the U.S. Department of Health & Human Services International Compilation of Human Subject Protections found at http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html and may utilize a consultant with knowledge of the laws and practices of the country.

WHAT ABOUT COMMUNICATION WITH THE IRB & LOCAL AUTHORITIES?

Communication with the IRB and Local Authorities

With the research occurring outside of the country there should be consideration on how the communication between the researcher and the Office of Institutional Research & Effectiveness will take place. The protocol should describe the following:

i. How communication will occur with the IRB and the local Ethics Committee

ii. How ongoing review, amendments, or reporting of unanticipated problems or complaints will be handled and by whom.

iii. If it is a student researcher abroad, the student's knowledge of the country and how the student will communicate with their faculty advisor. iv. List a local contact in case principal investigator or faculty sponsor cannot be reached.

QUESTIONS