

TEXAS WOMAN'S UNIVERSITY

Institutional Review Board Procedures

Federalwide Assurance # FWA00000178

June 2018

TABLE OF CONTENTS

INTRODUCTION	4
ROLES AND RESPONSIBILITIES.....	4
TWU Researchers	4
Institutional Review Board (IRB).....	4
Provost (Authorized Institutional Official).....	4
Vice Provost for Research.....	4
Director of Operations, Research & Sponsored Programs.....	5
Research Compliance Coordinator.....	5
IRB Chair	5
IRB Co-Chair.....	5
ORSP Project Coordinator	5
Principal Investigator (PI)	5
Faculty Advisor	7
Unit Administrator (Department Chair, Program Director, Associate Dean).....	8
Institution (TWU).....	8
DEFINITIONS.....	8
Adverse Events	8
Human Subject	8
Intervention.....	9
Informed Consent.....	9
Minimal Risk	9
Noncompliance.....	9
Principal Investigator (PI)	9
Protocol	10
Research	10
Risk10	
Unanticipated Problems.....	11
Vulnerable Populations	11
COMMITTEE MEMBERSHIP AND GUIDELINES.....	11
IRB Membership.....	11
Member Appointments and Terms.....	12
REQUIRED HUMAN SUBJECTS TRAINING	12
CATEGORIES OF REVIEW	13
Exempt Review	13
Expedited Review	14
Full Review.....	14
IRB OPERATIONS AND FUNCTIONS	15
IRB Functions	15
Convened Meetings.....	15
Criteria for Review.....	16
Adverse Events or Unanticipated Problems.....	17

Reporting Requirements.....	18
Noncompliance.....	18
Minor Noncompliance	19
Serious and Continuing Noncompliance.....	19
Actions and Notifications after Determination of Serious or Continuing Noncompliance	20
Reporting Requirements.....	21
Appeal of Noncompliance.....	21
Suspension or Termination of Approval.....	22
Continuing Protocol Reviews.....	22
Review of Research for Sponsored Projects.....	22
Review of Research by Other Institutional Compliance Committees	22
Research at TWU by Investigators from Other Institutions	22
Research Conducted at Non-TWU Sites that Requires Approval by a Non-TWU IRB	23
Dual Review	23
EVALUATION OF RISK	25
Physical Harms.....	26
Psychological Harms.....	26
Social Harms	26
Economic Harms.....	26
GENERAL REQUIREMENTS FOR OBTAINING INFORMED CONSENT	26
Basic Elements of Informed Consent	27
Documentation of Informed Consent	28
VULNERABLE POPULATIONS	29
Children	29
Prisoners.....	30
Pregnant Women, Fetuses, and Neonates.....	31
STUDIES INVOLVING DECEPTION	31
HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA)	32
INITIAL REVIEW OF RESEARCH	32
Submission of Application	32
Possible Actions.....	33
Approved Protocols.....	33
Disapproved Protocols	34
INTERIM REVIEW PROCEDURES	34
Review of Proposed Changes in Research Projects (Modifications).....	34
Continuing Review of Research (Extensions)	34
CLOSEOUT OF IRB PROTOCOL	35
IRB RECORDS.....	35

INTRODUCTION

It is the policy of Texas Woman's University (TWU) that all research conducted by any TWU faculty member, staff member, or student using human subjects must have prior approval from a TWU Institutional Review Board (IRB) before the research is initiated (see *TWU Policy 1.15 Human Subjects Research*). The TWU IRBs on each campus (Denton – IRB #00000829, Dallas – IRB #00000844, and Houston – IRB #00000845) review and approve research involving human subjects. The IRBs operate under Federalwide Assurance # FWA 00000178 issued by the U.S. Department of Health and Human Services (DHHS).

ROLES AND RESPONSIBILITIES

TWU Researchers

All TWU faculty members, staff members, or students conducting research using human subjects must have prior approval from a TWU IRB before the research can begin.

Institutional Review Board (IRB)

The TWU IRB is responsible for providing independent review and oversight of research involving human participants without undue influence from non-IRB members. The IRB shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy. The IRB is an administrative body established to protect the rights and welfare of human participants in research activities conducted under the auspices of the institution with which it is affiliated. The IRB has the authority to approve, require modification of, or disapprove all research activities that fall within its jurisdiction, as specified by federal regulations and local institutional policy. The fundamental responsibilities of the IRB include determining the risks and potential benefits of investigations, ascertaining the appropriateness of the methods used to obtain consent, and protecting the rights and welfare of the individuals involved.

The IRB is responsible for providing written notification of its findings and actions including approval or disapproval of protocols and written reminders of renewal dates to investigators. The IRB is also responsible for providing written reports of its findings and actions to the Provost. The reports are delivered to the Office of the Provost on a monthly basis.

Provost (Authorized Institutional Official)

The Provost, as the Authorized Institutional Official, is authorized to act for the University and, on behalf of the University, obligates TWU to the Terms of the Federalwide Assurance (FWA). The Provost is the point of responsibility for the oversight of research and IRB functions.

Vice Provost for Research

The Vice Provost for Research, as the Human Protections Administrator, serves as primary point of contact with the Office for Human Research Protections (OHRP) for questions related to

TWU's FWA or other matters that may arise and directs the Coordinator of Research Compliance and the Director of Operations in designing and implementing a University-wide program on research compliance and assuring compliance with internal and external standards and regulations.

Director of Operations, Research & Sponsored Programs

The Director of Operations creates procedures to maintain and track compliance for the IRBs, assists with planning and implementing programs of education and training for researchers, and maintains database and other electronic processes for the operation of the IRBs. The Director of Operations may assume the duties of the Vice Provost for Research in his/her absence.

Research Compliance Coordinator

The Research Compliance Coordinator collaborates with the Vice Provost for Research and the Director of Operations to design, implement and assure compliance with regulatory requirements of the Institutional Review Board.

IRB Chair

The IRB Chair presides over regular meetings of the IRB and reviews applications and other documents in accordance with the *Code of Federal Regulations* ([45 CFR 46](#)). The Chair conveys the decisions of the IRB via written notifications.

IRB Co-Chair

The Co-Chair assists with the duties of the Chair, assumes the duties of the Chair in his/her absence, including presiding over meetings when Chair is unable to attend.

ORSP Project Coordinator

ORSP Project Coordinators serve in an administrative capacity for the IRBs. Coordinators act at the direction of the IRBs by providing support and clerical services but are not authorized to participate in IRB decisions.

Principal Investigator (PI)

The Principal Investigator (PI) is ultimately responsible for assuring compliance with applicable University and Federal IRB policies and procedures and for the oversight of the research study and the informed consent process. Although the PI may delegate tasks to members of his/her research team, s/he retains the ultimate responsibility for the conduct of the study.

A PI must be a TWU faculty member, staff member, or student. All faculty members may serve as PI (with approval from their unit administrator). Staff may serve as PI if they have appropriate qualifications to conduct the research and if they have obtained approval to conduct the research from their immediate supervisor. Students may serve as principal investigators for their own research projects and are responsible for submitting the IRB application. However, when a student is listed as the PI, a faculty advisor must be listed on the protocol submission. If a

student from another institution is also a staff member at TWU, a faculty advisor is not required. In these circumstances, all requirements listed above under “Staff” must be met.

The PI is responsible for conducting the study in strict accordance with the current IRB-approved research protocol. Any change to an approved protocol must be approved using established modification procedures except where a change may be necessary to eliminate an apparent immediate hazard to a given human research subject.

Co-Investigators and Other Research Team Members

Appropriately qualified co-investigators and research team members may perform tasks as delegated by the Principal Investigator but they do not accept primary responsibility for the research study. General responsibilities of the co-Investigators and other research team members include:

- completing required institutional and protocol specific training;
- adhering to the federal regulations, state and local laws, institutional policies and procedures surrounding the safety and protection of human participants;
- assuring participant privacy and confidentiality according to IRB guidelines and any other applicable regulations (e.g., HIPAA, FERPA, etc.).

Research team members are defined as “individuals responsible for the design, conduct, or reporting of research.” Research team members are engaged in the research when they (i) intervene or interact with living individuals for research purposes; or (ii) obtain individually identifiable private information for research purposes. Only those key personnel that are “engaged in the research” must take the mandatory human studies education modules. In the following examples, these personnel are engaged in the research:

- A statistician who will design the statistical analysis procedures to be used in the research study and then carry out these procedures once the data is received. This individual is involved in the design and execution of the research.
- A nurse who will provide information on the study, explain what is involved in the study, do an initial screening to see if the individual meets inclusion criteria, and consent all eligible participants.

In the examples below, human subjects training is not mandatory as these individuals are not engaged in research activities:

- A statistician who will receive de-identified research data once it has been collected to analyze data.
- A consultant who will provide guidance and expertise in designing the protocol but the protocol will actually be written by the PI.

- Any staff member performing their normal duties that contribute to the project but are not engaged in the research (e.g., a receptionist handing out flyers, a phlebotomist performing blood-draws, transcriptionists, translators).

Faculty Advisor

Students may serve as principal investigators for their own research projects and are responsible for submitting the IRB application. However, when a student is listed as the PI, a faculty advisor must be listed on the protocol submission. This faculty advisor must have a current TWU faculty appointment. The faculty member is considered the responsible party for assisting the PI in making ethical decisions throughout the life of the project. The IRB holds the faculty advisor(s) responsible for the overall management of an approved research protocol in conjunction with the student PI. Management of the research encompasses the ethical, administrative, fiscal, and applied elements of a project. Faculty Advisors are required to:

- acknowledge and accept their responsibility for protecting the rights and welfare of human research participants,
- ensure the student and faculty advisor have sufficient training and experience to conduct the research in accordance with the protocol,
- fulfill the IRB training requirement and understand the ethical standards and regulatory requirements governing research activities with human participants,
- collaborate with student PIs during the preparation of an IRB proposal and ensure the proposed research complies with the ethical principles outlined in the [Belmont Report](#), human subject research regulations including [45 CFR 46](#), internal policies, and other applicable federal or state laws,
- report any real or potential conflicts of interests in compliance with the conflict of interest policies,
- make adequate time to consult with the student PI on a regular basis to monitor research progress,
- assist and supervise the researcher in problem solving in the event a problem, emergent question or concern were to surface,
- ensure all research activities have IRB approval and other approval required by the institution before human subjects are involved, and implement the research activity as it was approved by the IRB,
- ensure student PIs promptly report any adverse events, protocol deviations, or other unanticipated problems involving risks to participants or others and other reportable events to the IRB in a timely manner,

- ensure a Study Close Request is submitted to the IRB upon completion of the research. In the event that the PI is unable or unwilling to do so, the responsible faculty advisor will be required to do so prior to when the PI graduates or otherwise leaves TWU, and
- ensure the student PI is in compliance with the additional responsibilities listed as investigator responsibilities.

Unit Administrator (Department Chair, Program Director, Associate Dean)

The unit administrator is responsible for reading, reviewing, and approving the content of the application and for assuring that the PI (and faculty advisor for student research) meet the qualifications and requirements and adhere to the ethical principles outlined in the TWU IRB regulations.

Institution (TWU)

Research covered by this policy that has been approved by the IRB may be subject to further appropriate review and approval or disapproval by the Provost. However, the Provost may not approve the research if it has not been approved by the IRB.

DEFINITIONS

Adverse Events

An *adverse event* is any untoward or unfavorable occurrence in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Adverse events encompass both physical and psychological harms.

- ***Internal adverse events:*** adverse events experienced by subjects enrolled by an investigator at TWU whether as a part of a multi-center study or solely as a TWU study.
- ***External adverse events:*** adverse events experienced by subjects enrolled by investigators at other institutions engaged in a multi-center study in which TWU is participating.

Coercion (Undue Influence)

Coercion occurs when an overt or implicit threat causes the participant to act in a way that is contrary to their own interest. For example, an investigator might tell a prospective subject that he or she will lose access to needed health services if he or she does not participate in the research.

Human Subject

Human subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens;

or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention

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

Informed Consent

Informed Consent is a person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.

Minimal Risk

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.

Noncompliance

Noncompliance is the failure to comply with federal or state regulations, TWU policies and procedures governing research with human subjects, or requirements of the IRB.

- **Minor Noncompliance** is a deviation from procedures that does not increase risks to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data or the IRB process.
- **Serious Noncompliance** is an act or omission that has the potential to increase risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data or IRB process.
- **Continuing Noncompliance** is noncompliance that has been previously reported, or a pattern of ongoing activities that indicate a lack of understanding of human subjects protection requirements that may affect research participants or the validity of the research and suggest the potential for future noncompliance without intervention.

Principal Investigator (PI)

The *Principal Investigator (PI)* has primary responsibility for the research project. The PI may be a TWU faculty member, staff member, or student, depending on the nature of the project. All research in which a student is the PI must be supervised by a TWU faculty advisor with a current appointment.

Private Information

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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record). Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Protocol

Protocol is the description of research or related projects presented to the IRB for review. Research projects may encompass several individual investigations using related techniques or common themes. The proposed projects must be presented in sufficient detail to enable the IRB to determine whether adequate provisions have been made for the protection of the subjects' rights and welfare.

Research

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 purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Risk

The OHRP IRB Guidebook defines *risk* as the probability of harm or injury occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. The risks to which research subjects may be exposed have been classified as physical, psychological, social, and economic [Levine (1986), p. 42]. The

determination of such risk is a matter of sound professional judgment and responsibility by the IRB as well as the investigators (see *Evaluation of Risk* section for further detail).

Unanticipated Problems

An *unanticipated problem* is any incident, experience, adverse event, or outcome that meets all of the following criteria: unexpected given the described procedures, informed consent, and population characteristics; related or possibly related to participation in the research; suggests that subjects are placed at greater risk than previously known.

Vulnerable Populations

Vulnerable populations include special populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons for which special safeguards should be considered.

COMMITTEE MEMBERSHIP AND GUIDELINES

IRB Membership

The IRB shall have at least five members. The IRB shall be sufficiently qualified through the experience, expertise, and diversity of its members, including race, gender, cultural background, and sensitivity to community attitudes. In addition to the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable laws, and standards of professional conduct and practice. The IRB shall include persons knowledgeable in these areas. The IRB shall also include persons knowledgeable in working with individuals in vulnerable populations.

In addition to possessing the professional competence necessary to review specific research activities, the IRB membership will possess the following attributes.

- The IRB will be composed of both male and female members.
- The IRB will be composed of members representing more than one profession.
- The IRB will include at least one member who is not otherwise affiliated with the institution. *Unaffiliated member* means an IRB member who has no affiliation with the University except as a member of the IRB. Persons retired from the University or those who have family members (spouse, parent, children) employed by the University are not considered unaffiliated.
- The IRB will include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

- The IRB will not permit a member to participate in the initial or continuing review of any project in which that member has a conflicting interest, except to provide information as requested by the IRB.
- The IRB may invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.
- IRB members are appointed or re-appointed annually by the Provost. IRB members will receive a letter of appointment or reappointment annually.

Member Appointments and Terms

The Vice Provost for Research, in consultation with the IRB Chair and members of the IRB, will solicit nominations and names from the Faculty Senate committee volunteer list to fill vacant positions on the IRB. Candidates need not have specific qualifications. Candidates may be sought for expertise or to meet federal IRB composition requirements. All nominees are subject to approval by the Provost.

IRB members serve initial three-year terms. Members who are adequately performing required duties may be reappointed for unlimited one-year terms. IRB duties include regular attendance at convened meetings, timely review of assigned IRB applications, and submission of current CV and training certificates. All reappointments are subject to approval by the Provost.

The IRB Chair serves a three-year term and may be appointed for a subsequent two-year term. IRB terms begin in the fall semester. Members are encouraged to serve as Co-Chair before assuming the role of Chair. Duties of the IRB Chair consist of presiding over regular meetings of the IRB and reviewing applications and other documents in accordance with [45 CFR 46](#). The Co-Chair assists with the duties of the Chair and presides over meetings in the Chair's absence. The Co-Chair serves a one-year term.

Members who are unable to attend meetings for extended periods of time must inform the Chair in writing. Replacements may be appointed. Members may be removed by the Chair or the Vice Provost for Research for poor attendance or failure to complete required duties.

A current roster of IRB members including degrees, employment information, or position at TWU must be on file with OHRP. Changes in IRB membership shall be reported to the OHRP, DHHS, or any successor office within 90 days of the change.

REQUIRED HUMAN SUBJECTS TRAINING

All individuals (including but not limited to PIs, research assistants, faculty advisors, and staff) engaged in research with human subjects are required to successfully complete approved training in the protection of human research participants. A link to online training options is available at <https://www.twu.edu/institutional-review-board-irb/>. A current training certificate (no more than 3 years old) must be on file for all research team members before an exemption,

approval, or extension can be granted. This required training applies to TWU personnel on all studies regardless of the level of review.

A Confidentiality Agreement Form may be signed in lieu of the required training by individuals who have access to identifiable information but are not part of the research team.

CATEGORIES OF REVIEW

Exempt Review

Studies that meet the criteria as provided in the federal regulations may be reviewed using the exempt review process. Studies involving prisoners except for research aimed at involving a broader subject population that only incidentally includes prisoners cannot be exempted. Exempt applications will be reviewed by one IRB member (usually the Chair) to determine, based on federal guidelines, whether a project is **Exempt from further IRB review**. The IRB chair may delegate the responsibility to review exempt protocols to an ORSP staff member or another IRB member for non-funded research. A listing of federally approved exemptions is provided below.

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or

(ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

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

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

(i) Public benefit or service programs;

(ii) procedures for obtaining benefits or services under those programs;

(iii) possible changes in or alternatives to those programs or procedures; or

(iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,

(i) if wholesome foods without additives are consumed or

(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited Review

Expedited reviews are carried out by the IRB Chair or one or more (generally three) experienced members designated by the Chair. Reviewers are designated based on expertise in disciplines of studies and on a rotating basis when possible. Expedited protocol applications are sent to designated reviewers as soon as they are received by the IRB. In conducting expedited reviews, the IRB member(s) may exercise all of the authorities of the IRB except that they may not disapprove the research. A research activity may be disapproved only after review by the convened IRB in accordance with the non-expedited procedure set forth in [45 CFR 46](#). Outcomes of expedited reviews are included in monthly activity reports to the IRB.

Research activities that (1) involve no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories listed in the *Federal Register* (63 FR 60364-60367) may be reviewed by the IRB through the expedited review procedure as authorized by [45 CFR 46](#). A list of research categories may be found on the [OHRP website](#). Expedited review procedures may also be used to review minor changes in previously approved research during the period for which approval is authorized.

Full Review

Studies that cannot be exempted based on the exemption categories or receive a review using the expedited procedures as defined above must be reviewed at a fully convened meeting of the IRB.

Full Review application packets including the protocol, consent documents, recruitment materials, and data collection materials are distributed to all IRB members prior to meetings. Full

Review applications are reviewed at convened meetings with a majority of members present, including at least one member with concerns in nonscientific areas.

The IRB Chair may designate primary reviewer(s) as needed to manage the volume of applications. Primary reviewers are designated by the Chair on a rotating basis. The role of a primary reviewer is to review application materials in detail and submit written recommendations to the committee for discussion on changes or clarifications necessary to approve a protocol.

IRB OPERATIONS AND FUNCTIONS

IRB Functions

The function of the IRB is to review and approve, require modifications in, or disapprove all research activities with human subjects. The IRB will notify investigators and appropriate University administrators, in writing, of decisions to approve, require modifications in, or disapprove proposed research activities. When the IRB disapproves research activities, the written notification will include the reasons for the decision and offer investigators the opportunity to respond in person or in writing.

The IRB may identify studies that require interim verification that no material changes have occurred since previous IRB reviews. Selection of projects to be reviewed may be random or may be based on investigator history, or project complexity. Sources other than investigators such as study participants, faculty advisors of student PIs, or faculty members' supervisors may be used in this process.

The IRB requires that all human subjects be given all relevant information about the research activities as part of the informed consent process. The IRB may require that additional information be provided to research subjects when the IRB determines that the information would meaningfully add to the protection of the rights and welfare of the subjects. The IRB will require documentation of informed consent or may waive documentation of informed consent in accordance with these procedures (see *General Requirements for Obtaining Informed Consent* for details of the informed consent process). The IRB has the authority to observe or have a third party observe the informed consent process and the research.

Convened Meetings

The IRBs meet according to meeting schedules and submission deadlines posted on the IRB website under the individual campus sections. The IRB may cancel scheduled meetings if there are no items that require review.

A quorum at a convened IRB meeting shall consist of more than one-half of the total membership including at least one member with a non-scientific focus. A voting majority of members at a convened meeting shall consist of more than one-half of the members present.

The IRB Chair may abstain from voting in a convened meeting unless necessary to make a

quorum or to break a tie vote. IRB members may abstain from voting by personal choice. Members who have a conflict of interest in a study shall recuse themselves from voting and leave the room to eliminate any chance of influencing the procedure. Conflicts of interest may include but are not limited to: conflicts of interest as defined by University policies and review of protocols in which an IRB member is the principal investigator, a research team member, or a faculty advisor.

Adequate minutes of all meetings and the monthly activity reports, which provide the results of reviews of all research protocols submitted to the IRB, are sent to IRB members. Monthly activity reports are also sent to the Provost. Minutes and the monthly activity reports are maintained in the IRB Offices on the Denton and Houston campuses. The monthly activity report including the outcomes of Exempt and/or Expedited reviews, adverse events on active projects, and annual extension requests will be approved, modified, or disapproved by a majority of members present.

The IRB may conduct convened meetings by telephone or video conference as long as members have received copies of all documents to be reviewed, a majority is present, and discussion occurs in real time. All members must be connected simultaneously for teleconferences or video conferences. "Telephone polling" (in which IRB members are contacted individually) does not qualify as a convened meeting.

Investigators may be asked to attend or may request to attend relevant portions of IRB meetings when the need exists to clarify research procedures or to answer questions regarding applications. Students may also be granted permission to attend IRB meetings for educational purposes.

Criteria for Review

The IRB reviews each protocol to determine that the following requirements are met:

- Risks to participants are minimized.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result. The IRB considers only those risks and benefits that may result from the research, and not risks or benefits that would likely result even if persons did not participate in the research.
- Selection of participants is equitable. When considering the selection of participants, the IRB will be particularly cognizant of the purpose and setting of research involving vulnerable populations.
- Informed consent will be sought from all prospective participants or the participants' legally authorized representatives in accordance with and as required by [45 CFR 46](#).
- Informed consent will be appropriately documented in accordance with, and to the extent required by, [45 CFR 46](#).

- The research plan makes adequate provision for monitoring the data collected to ensure the safety of participants as deemed appropriate by the IRB.
- Adequate safeguards are provided to protect the privacy of participants and to maintain the confidentiality of data as deemed appropriate by the IRB.

Adverse Events or Unanticipated Problems

An *adverse event* is any untoward or unfavorable occurrence in a human subject, including any abnormal sign, symptom, or disease, temporally associated with the subject's participation in the research, **whether or not considered related to the subject's participation in the research**. Adverse events encompass both physical and psychological harms (see *Definitions*).

An *unanticipated problem* is any incident, experience, adverse event, or outcome that meets all of the following criteria: unexpected given the described procedures, informed consent, and population characteristics; related or possibly related to participation in the research; suggests that subjects are placed at greater risk than previously known (see *Definitions*).

Adverse events and unanticipated problems are not mutually exclusive. An adverse event is not necessarily an unanticipated problem and vice versa. The IRB makes the final determination on categories of incidents.

- TWU investigators shall verbally report adverse events or unanticipated problems to the IRB within two (2) working days of knowledge of the incident and shall submit an IRB Incident Report Form to the IRB Office within five (5) working days. If the Incident Report Form is incomplete when initially submitted, a completed report form must be submitted to the IRB before the close of the study.
- The IRB Incident Report Form shall include at a minimum: name of PI, title of research project, award information (if applicable), a detailed description of the incident, a detailed description of actions or plans to address the incident, and the outcome.
- When reviewing reports of unanticipated problems and adverse events, the IRB shall consider whether the affected research protocol continues to satisfy the requirements for IRB approval, whether risks to participants continue to be minimized and reasonable in relation to the anticipated benefits to the participants, and the importance of the knowledge that may be reasonably expected to result.
- The IRB Chair may call an emergency meeting of the IRB or suspend research activities if necessary to prevent immediate threat to the safety and well-being of research subjects. Notification of suspensions or terminations will include the rationale for the IRB's action and will be sent by the IRB to investigators, faculty advisors of student investigators, the academic unit administrator, appropriate institutional officials, and the funding agency head if applicable.
- The IRB is authorized to require additional information from the investigator and/or require any modifications necessary to ensure the safety and wellbeing of research subjects and

ensure that such incidents will not happen again, either with the investigator or the protocol in question. Changes to a research study proposed by the investigator in response to an unanticipated problem must be reviewed and approved by the Chair or Co-Chair before being implemented, except when necessary to eliminate apparent immediate hazards to participants. If the changes are determined by the Chair or Co-Chair to be more than minor, the changes must be reviewed and approved by the convened IRB.

Reporting Requirements

The IRB shall promptly report unanticipated problems or incidents to the Vice Provost for Research. ORSP shall prepare required reports to the Provost, OHRP and the supporting agency head. The time frame for reporting will be based on the nature and severity of the incident and be in accordance with applicable [45 CFR 46](#) regulations or the OHRP Guidance on Reporting Incidents to OHRP at <http://www.hhs.gov/ohrp/compliance/reports/>.

Reports to OHRP, supporting agency heads, and the Provost on unanticipated problems shall include: name of the institution, name of PI, title of the research project, award information (if applicable), a detailed description of the incident, actions TWU is taking or plans to take to address the problem (e.g., protocol revision, suspension of participant enrollment, termination of research).

Noncompliance

Noncompliance is the failure to comply with federal or state regulations, TWU policies and procedures governing research with human subjects, or requirements of the IRB. Categories of noncompliance are *minor noncompliance*, *serious noncompliance*, and *continuing noncompliance*. The safety and wellbeing of research participants shall be the primary concern when addressing acts of noncompliance.

All institutional members, research participants, and others are encouraged to report observed or suspected noncompliance. Noncompliance may also be discovered through documents such as new applications, reviews, or adverse event reports as well as through processes such as internal audits, mass emails, or research presentations.

Reports of noncompliance should be made to the IRB. The recipient of the noncompliance report will immediately notify the IRB Chair. The IRB Chair, or another IRB committee member designated by the Chair, will review the report and associated information. If more information is needed, the IRB chair or IRB staff will communicate with the needed parties. If the reviewer determines that the report is unsubstantiated, no further action will be taken. If the reviewer determines that the report is substantiated, the IRB Chair or designee will make a determination of minor noncompliance, serious noncompliance, or continuing noncompliance; and the Vice Provost for Research will be notified.

The IRB Chair may call an emergency meeting of the IRB or suspend research activities if necessary to prevent immediate threat to the safety and well-being of research subjects. Notification of suspensions or terminations will include the rationale for the IRB's action and will be sent by the IRB to investigators, faculty advisors of student investigators, the academic unit

administrator, Dean, other appropriate institutional officials as the IRB deems necessary, and the funding agency head if applicable.

Minor Noncompliance

Minor noncompliance is a deviation from procedures that does not increase risks to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data or the IRB process. Examples may include but are not limited to:

- Lapses in continuing IRB approval for expedited and full-review studies *
- Failure to obtain exempt determination before exempt research is conducted;
- Initiation of research on protocols pending IRB approval;
- Minor changes in or deviations from an approved protocol;
- Deviations from an approved consent procedure; and
- Administrative errors.

* Protocols expire automatically when IRB approval lapses. Investigators will be notified of the approval lapse, given 30 days to submit an extension request, and informed that recruitment and data collection must cease immediately. If the extension request is not received within the 30-day period, the protocol will be closed and a new IRB application must be submitted if the investigator wishes to continue with the study. Lapses in IRB approval are considered minor noncompliance providing that all research activities have ceased. Research activities conducted during a lapse in IRB approval are considered serious noncompliance and will be reported according to DHHS regulations.

Minor noncompliance may be addressed by a notification from the IRB and/or IRB Chair to the investigator that includes the nature of the noncompliance, a corrective action plan, and a time frame for completion. Copies of notification letters may be sent to faculty advisors, academic unit administrators, Deans, Dean of the Graduate School, and other entities as deemed necessary by the IRB. Failure to respond to notification letters may be considered by the IRB to be either serious or continuing noncompliance.

Serious and Continuing Noncompliance

Serious noncompliance is an act or omission that has the potential to increase risk to research participants, compromise participants' rights or welfare, or affect the integrity of the research/data or IRB process. Examples may include but are not limited to:

- Failure to obtain IRB approval on expedited or full review studies before starting research;
- Continuing research activities after IRB notification that approval has expired;
- Failure to notify the IRB of changes in approved procedures, scope/intent of the study;
- Failure to monitor data to ensure safety of participants;
- Failure to report serious unanticipated problem involving risks to participants or others, including adverse events;
- Failure to adequately protect participant privacy and confidentiality of data;
- Failure to obtain informed consent;
- Failure to protect participants from coercion or undue influence;

- Failure to recruit participants according to IRB approved protocol;
- Failure to conduct research according to the IRB approved protocol; and
- Failure to maintain complete records of informed consent.

Continuing noncompliance is noncompliance that has been previously reported, or a pattern of ongoing activities that indicate a lack of understanding of human subjects' protection requirements that may affect research participants or the validity of the research and suggest the potential for future noncompliance without intervention. Examples may include but are not limited to:

- Repeated failure to provide or review progress reports resulting in lapses of IRB approval;
- Inadequate oversight of ongoing research; and
- Failure to respond to or resolve previous allegations or findings of noncompliance.

The IRB Chair, or one or more members designated by the Chair, shall investigate reports of serious or continuing noncompliance based on information gathered with the assistance of ORSP. The IRB will notify the investigator, the investigator's direct supervisor (for faculty / staff research), and faculty advisor (for student research) of the initiation of an investigation. The IRB Chair or designee shall report findings and recommendations to the full IRB at a convened meeting. At that meeting, the IRB will make the final determination regarding noncompliance and the appropriate corrective actions required, if any. The investigator may be required to attend this IRB meeting. The following documents, as applicable, will be sent to IRB members prior to the meeting at which the report of noncompliance is reviewed:

- Initial report of noncompliance;
- Written reports of findings and recommendations by the reviewing members;
- Any other reports generated during the investigation;
- Copies of most recently approved documents including application, protocol, consent documents, and any other relevant documents;
- Minutes of meetings in which the protocol was discussed;
- Any correspondence from the investigator; and
- Reports of any interviews conducted.

Actions and Notifications after Determination of Serious or Continuing Noncompliance

The IRB will review the information and decide if serious or continuing noncompliance has occurred. If it is determined that serious or continuing noncompliance has occurred, the IRB will list remedial actions to be taken to mitigate any possible harm or risks to subjects (past or future). These actions may include but are not limited to:

- Require modification of the research protocol;
- Require modification of the information that must be disclosed in a consent form;
- Require that current study participants be notified of the noncompliance when such information may affect willingness to continue participation;
- Require re-consent of all participants;
- Modify the continuing review schedule;

- Monitor research activities;
- Monitor the consent process;
- Suspend research activities until corrective actions are implemented;
- Terminate the research; and
- Other actions necessary to protect the study subjects.

If the IRB determines that serious or continuing noncompliance occurred, the IRB will notify the investigator and list any remedial actions and a timeframe for completion of such actions. A copy of this notification will be sent to the following:

- Provost
- Academic Unit Administrators;
- Investigator's Dean;
- Dean of Graduate School;
- Research Advisor; and
- Vice Provost for Research.

If the IRB determines that no serious or continuing noncompliance occurred, the IRB will notify the investigator, the investigator's direct supervisor (for faculty / staff research), and faculty advisor (for student research).

Reporting Requirements

ORSP shall prepare required reports to the Provost, OHRP and the supporting agency head. The time frame for reporting will be based on the nature and severity of the incident and be in accordance with applicable [45 CFR 46](#) regulations or the OHRP Guidance on Reporting Incidents to OHRP at <http://www.hhs.gov/ohrp/compliance/reports/>.

Reports to OHRP, supporting agency heads, and the Provost on serious or continuing noncompliance shall include: name of the institution, name of PI, title of the research project, federal award information (if applicable), a detailed description of the incident, actions TWU is taking or plans to take to address the problem (e.g., protocol revision, suspension of participant enrollment, termination of research).

The Provost and/or Dean may take disciplinary action against the investigator for violation of University policies and regulations.

Appeal of Noncompliance

PIs may appeal IRB decisions regarding noncompliance by submitting a brief summary and supporting documentation outlining the reasons for the appeal to IRB. Appeal for minor noncompliance will be reviewed by the chair or a delegate of the chair. If the appeal is upheld, the issue will be considered closed. However, if the reviewer upholds the initial determination of noncompliance, then the appeal will be reviewed by the IRB at a convened meeting. All appeals for serious or continuing noncompliance must be reviewed by the full IRB. PIs who appeal may be asked, or can request, to attend the convened IRB meeting in which the appeal is reviewed. The IRB may also request that the faculty advisor attend this meeting.

Suspension or Termination of Approval

The IRB has the authority to suspend or terminate approval of research that is not conducted in accordance with IRB requirements or is associated with unexpected serious harm to participants, adverse events, unanticipated problems, or serious or continuing noncompliance. Researchers must not recruit participants, enroll participants, or collect data in any form when research studies have been suspended or terminated. Data collected during periods of suspension or termination must be discarded and may not be used in any capacity for research projects.

Any suspension or termination of approval will include a statement of the reasons for the IRB's action and will be reported promptly to investigators, faculty advisors of student investigators, the academic unit administrators, the Provost, OHRP, and the funding agency head.

Continuing Protocol Reviews

All research protocols approved by the IRB as Expedited or Full Reviews shall be reviewed periodically. Intervals between consecutive reviews may not exceed 12 months. The interval between consecutive reviews may be less than twelve months if the IRB determines more frequent reviews are needed. The IRB Chair can approve extensions for full review studies where only data analysis is being done (subject recruitment and data collection are no longer taking place).

Review of Research for Sponsored Projects

Proposals for federal funding involving human subject research must be reviewed in conjunction with standard IRB review procedures. Research & Sponsored Programs may also require that proposals for non-federal funding be reviewed by the IRB to comply with funding agency requirements or as necessary to maintain the protection of human subjects in research taking into consideration the size of the award, complexity of the project, experience-level and history of investigator, etc. If review of the proposal is required, all sections of the proposal that address human subject research methodology will be provided to the IRB for review at the award stage. The proposal information will be reviewed by the IRB chair or their designee to assure consistency with the approved IRB protocol. The Office of Research & Sponsored Programs will assist the principal investigator and the IRB to assure that the IRB completes the review.

Review of Research by Other Institutional Compliance Committees

Investigators must inform the IRB if, in addition to IRB approval, the research must be reviewed and approved by other institutional compliance committees such as the Radiation Safety committee or the Institutional Biosafety Committee (IBC).

Research at TWU by Investigators from Other Institutions

Researchers who are not affiliated with TWU may recruit TWU faculty members, staff members, or students as participants if approval has been granted by another IRB. Although such studies do not require the involvement of the TWU IRB, approval by instructors, academic unit administrators, or deans may be necessary. Faculty members or administrators who approve such studies should verify that the research protocol has received IRB approval.

Research Conducted at Non-TWU Sites that Requires Approval by a Non-TWU IRB

Studies conducted at offsite institutions may require approval by the offsite institution's IRB. TWU requires that studies also be reviewed and approved by the TWU IRB (dual review). Under certain circumstances, TWU may enter into an agreement that authorizes an offsite IRB to serve as the IRB of record. Such agreements must be approved by the signatory officials of both institutions (see *IRB Authorization Agreement*).

Regardless of the approval method, consent documents must meet TWU requirements. The goal in all circumstances is a single consent form that explains the roles of each institution and fairly and completely represents the decisions of each IRB involved.

Dual Review

Unless an IAA is put in place, TWU requires that studies conducted at offsite institutions that require approval by the offsite institution's IRB also be reviewed and approved by the TWU IRB using the dual review process. (Refer to Research Conducted at Non-TWU Sites that Requires Approval by a Non-TWU IRB section for more detail regarding the IAA).

Consent documents must meet TWU standards. The goal would be to have one consent form for the study which informs the subject about his or her rights, the purpose of the study, the procedures, potential risks and benefits of participation, and identify each institution and their role. The TWU IRB may exercise some flexibility in determining the specifics of the consent and may take into consideration the roles of the various institutions and researchers.

An offsite-approved protocol is reviewed by TWU with the purpose of protecting the rights and welfare of study participants and in light of the fact that it has been approved by another IRB.

- The researcher's initial step after discerning that offsite IRB review is required is to review the requirements of both institutions in order to develop a single consent document that meets the standards of both. This step is critical in minimizing delays and preventing resubmissions.
- All offsite-approved protocols should be submitted for review at the level approved by the offsite IRB and will be reviewed as follows:
 - Full Review Studies will be reviewed at a fully convened meeting. The TWU IRB Chair will designate a primary reviewer who possesses expertise in the study discipline as well as dual review procedures.
 - Expedited Studies will be reviewed by the TWU IRB Chair or one reviewer designated by the Chair.
 - Exempt Studies will be reviewed by the IRB Chair or Co-Chair. Generally, an exempt study would not be submitted using the dual review application process. Instead, the exempt application form is usually more appropriate.

- Dual review applications must include a completed Dual Review Application form, the completed offsite IRB application with all associated materials (including the consent form), the offsite IRB approval letter, and any additional administrative requirements as determined by TWU policy. The Dual Review Application will also include the researcher's role in the study, name and role of the offsite PI, and offsite IRB contact information.

Dual review studies are subject to the same TWU IRB guidelines, reporting requirements, and deadlines as regular IRB applications. The TWU IRB is authorized to approve, disapprove, upgrade review levels, terminate, or suspend any study submitted for review regardless of the method of submission.

Institutional Authorization Agreement (IAA)

An IRB IAA is a written agreement prescribed by OHRP that describes the obligations of both parties when one relies on the other for IRB review and continuing oversight of one or more human subject research projects. IAAs must be signed by the signatory officials of each institution.

Each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.

An IAA must include descriptions of the regulatory requirements for each party and must be in compliance with the procedures of the TWU IRB.

Researchers must contact the Vice Provost for Research if they wish to initiate an IAA with an external study site. The Vice Provost for Research, in conjunction with the IRB Chair, will determine if an IAA is appropriate and, if so, will initiate the agreement process. The researcher may be required to provide information on the offsite IRB including but not limited to: application forms, consent form requirements and/or templates, review processes, and the institution's FWA.

The offsite institution must have an approved FWA on file with the OHRP and must meet the requirements set forth by TWU as the deferring IRB. If the research project in question involves Federal funding, the sponsoring agency must be informed of and approve the IAA. With or without the existence of an IAA, if Federal funding is involved, the other institution needs to have or obtain a FWA. The designated (offsite) IRB will report serious or continuing noncompliance, unanticipated problems involving risks to subjects or others, and/or suspensions or terminations of IRB approved research related to the TWU FWA to OHRP and other oversight agencies as appropriate.

The IAA shall, at a minimum, include:

- Procedures for communication between TWU and the Offsite IRB;
- Procedures for notification of findings, actions (terminations, suspensions), adverse events, or unanticipated problems to TWU;
- A provision stating that, if the Offsite Institution fails to notify TWU as stated above, TWU shall have the right to immediately terminate the agreement and request any study related documents associated with the TWU investigator's role in the study;
- A description of each institution's engagement in the research activity;
- Provisions that ensure that consent documents meet TWU requirements;
- The effective date and term of the agreement; and
- TWU shall retain ultimate authority and responsibility for the protection of human subjects enrolled in research conducted under its auspices regardless of the venue of IRB review.

Documents that must be provided to TWU by the researcher if an IAA is executed:

- IRB approval letter;
- Application documents including the FWA number and the IRB number of the offsite institution;
- Approved consent documents;
- Reports including, but not limited to, progress reports, extension reports, adverse event reports, and final reports;
- Protocol modifications; and
- Any correspondence between the researcher and the offsite IRB.

TWU may require additional review of research covered by an IAA and may impose additional administrative requirements as determined by TWU policy. The TWU IRB reserves the right to upgrade any review based on risk.

EVALUATION OF RISK

The IRB shall evaluate potential risks on a case-by-case basis and be sensitive to possible harms. If a research activity will expose individuals to risk, the IRB must be assured that:

- The rights and welfare of the individuals are adequately protected;
- The methods used to obtain informed consent are adequate and appropriate;
- The risks to individuals are outweighed by the potential benefits to individuals or society or by the importance of the knowledge to be gained;
- Study personnel are qualified to conduct the study, including any specialized procedures or testing; and
- Adequate provisions for "debriefing" or post-investigation explanations are included in studies involving deception or incomplete disclosure.

The IRB may call qualified consultants to serve as non-voting members when participants will be recruited from vulnerable populations. The IRB may also refer investigators to consultants for assessment of the potential risks and benefits of the proposed research. The IRB Chair will

contact the University's General Counsel when the IRB believes that a legal opinion is needed. Individuals are considered to be at risk if they may be exposed to physical, psychological, social, or economic harm.

Physical Harms

Research involving physical activities or medical interventions can expose participants to pain, discomfort, physical injury, injury from invasive medical procedures, or harm from possible side effects of drugs. These adverse effects are considered "risks" for purposes of IRB review. Research designed to measure the effects of therapeutic or diagnostic procedures applied in the course of caring for an illness may not entail any significant risks beyond those presented by medically indicated interventions. Research designed to evaluate new drugs or procedures may present more than minimal risk, and, on occasion, can cause serious or disabling injuries.

Psychological Harms

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). Stress, feelings of guilt, or embarrassment may arise from thinking or talking about one's own behavior or attitudes on sensitive topics such as drug use, sexuality, selfishness, or violence. Psychological harm can also occur when the environment of the participant is manipulated, when studies involve any form of deception, and when studies involve invasion of privacy.

Social Harms

Some invasions of privacy and breaches of confidentiality may result in embarrassment within one's business or social group, in loss of employment, or in criminal prosecution. Areas of particular sensitivity are information regarding alcohol or drug abuse, mental illness, illegal activities, and sexual behavior. Some social and behavioral research may yield information that could label or stigmatize participants. Confidentiality safeguards must be strong in these instances. Breaches of confidentiality can adversely affect present or future employment, eligibility for insurance, political campaigns, and standing in the community. A researcher's plans to contact such individuals for follow-up studies should be reviewed with care.

Economic Harms

Participation in research may also result in actual monetary losses to individuals such as transportation expenses, childcare expenses, and time off work. Any anticipated costs to research participants should be described in detail during the consent process.

GENERAL REQUIREMENTS FOR OBTAINING INFORMED CONSENT

Except as provided elsewhere in this policy, investigators may not involve a human being as a participant in research covered by this policy unless the investigator has obtained the legally effective informed consent of the participant or the participant's legally authorized

representative. Investigators may seek such consent only under circumstances that provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence.

The information that is given to the participant or the representative shall be in language understandable to the participant or the representative. Thus participants should be presented with consent documents and other research-related documents (such as questionnaires or cover letters) written in a language understandable to them. Any verbal explanation of the consent or research procedures should be presented in a language understandable to the participant. The IRB must receive all translated versions of the written documents as a condition of approval.

PIs assure the IRB by submission of the application that any translated documents are accurate. The IRB, at their discretion, may request additional information regarding translated documents. Translators involved only in translation of written documents are not required to fulfill the training requirement.

The consent process may not involve the use of exculpatory language through which the participant or representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, sponsor, institution, or agents from liability for negligence.

Basic Elements of Informed Consent

When seeking informed consent, the IRB suggests that the informed consent begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of informed consent should be organized and presented in a way that facilitates comprehension.

This presentation should then be followed by the required elements below:

- A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subject;
- A description of any benefits to the participant or to others which may reasonably be expected from the research;
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;

- For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- Contact information for answers to pertinent questions about the research and research participants' rights, and contact information in the event of a research-related injury to the participant; and
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

When appropriate, any of the following additional elements of informed consent may be required by the IRB.

- A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant) which are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- The approximate number of participants involved in the study.

Documentation of Informed Consent

Informed consent must be documented by the use of an IRB approved written consent form that contains all of the required elements of informed consent and has been signed by the participant or the participant's legally authorized representative. Participants must be provided with a copy of the consent forms.

Consent forms that have been approved by the IRB contain the official approval stamp indicating the date of approval. Stamped consent forms are sent to investigators with their IRB approval letters. Investigators are prohibited from using any other form without the prior approval of the IRB.

The IRB may waive the requirement for investigators to obtain signed, written informed consent from participants, if the IRB makes one of the following determinations:

- The only record linking participants to the research would be the consent document and the primary risk would be potential harm resulting from a breach of confidentiality.
- The research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of a research context.

VULNERABLE POPULATIONS

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, it is the responsibility of the IRB to make certain that additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Children

The IRB shall review research with children as participants and shall approve only research which satisfies the conditions set forth in Subpart D of [45 CFR 46](#). The CFR provides that educational and social research with children as participants may be considered Exempt and may not require signed informed consent (see Exempt Review). Expedited and Full Review research studies involving children require signed informed consent from parents or legal guardians.

The IRB, in accordance with 45 CFR Part 46.405, may approve studies with children that involve greater than minimal risk if the risk is justified by the anticipated benefit to the subjects, the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches, and adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

Research projects with children that involve greater than minimal risk but are likely to yield generalizable knowledge about the subject's disorder or condition may be approved by the IRB if the risk represents a minor increase over minimal risk; the intervention presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; the intervention is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and adequate provisions are made for soliciting assent of the children and permission of their parents or guardians. These requirements are in accordance with 45 CFR Part 46.406.

The IRB shall determine that adequate provisions are made for soliciting the assent of the children when, in the judgment of the IRB, the children are capable of providing assent. In determining whether children are capable of assenting, the IRB will take into account the ages, maturity, and psychological states of the children involved. This judgment may be made for all children involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the

participants are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived.

The IRB shall determine that adequate provisions are made for soliciting the permission of each child's parents or guardian in accordance with 45 CFR 46.408. The IRB may waive the consent requirements provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with federal, state, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

The IRB shall require appointment of an advocate for each child who is a ward of the state or any other agency, institution, or entity, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Prisoners

As prisoners may be under constraints due to their incarceration, which could impact their ability to make truly voluntary and un-coerced decisions whether or not to participate as participants in research, the IRB is obligated to provide additional safeguards for the protection of prisoners involved in research activities.

The CFR mandates that the majority of IRB members have no association with the prisons involved in research (apart from IRB membership) and that at least one member of the IRB must be a prisoner or have the appropriate background to serve as a prisoner representative.

The selection of research participants must be fair to all prisoners and immune from arbitrary intervention by prison authorities, parole boards, or other prisoners. The risks involved in this research must be commensurate with risks that would be accepted by non-prisoner volunteers.

The information must be presented in language that is understandable to the prison population. The benefits of the research must not be of such a magnitude that they impair the ability of prisoners to weigh the risks of the research given the limited choice environment of the prison. Adequate assurance must be provided to the IRB that parole boards will not consider prisoners' decisions about participation in research in making decisions regarding parole. All prisoners must be clearly informed, in advance, that participation in the research will have no effect on their parole. Where the IRB finds a need for any sort of follow-up procedures following participation, adequate provisions for prisoners must be made, taking into account varying lengths of prisoners' sentences, in order to inform prisoner participants of the follow-up.

Biomedical and behavioral research involving prisoners as research participants may be conducted only if (a) the above requirements have been met; and (b) the proposed research is solely for the following purposes:

- Possible causes, effects, and processes of criminal behavior or incarceration, with no more than minimal risk and inconvenience to participants;
- Prisons, as institutional structures, or prisoners, as incarcerated persons, with no more than minimal risk and inconvenience to participants;
- Conditions particularly impacting prisoners as a group, in that certain conditions are more prevalent in prisons than elsewhere (e.g., hepatitis, alcohol/drug addiction, sexual assaults), following consultation with appropriate experts and published notice in the Federal Register;
- Practices with the intent and reasonable probability of improving the health or well-being of participants. Where prisoners are to be assigned to control groups in which they may not benefit from the research, consultation with appropriate experts and published notice in the Federal Register are required.

Except as provided above, biomedical or behavioral research will not involve prisoners as research participants.

Pregnant Women, Fetuses, and Neonates

Research involving pregnant women, human fetuses, and neonates (i.e., newborns) is expected to present a reasonable opportunity to further the understanding, prevention, or alleviation of serious problems impacting the health or welfare of these populations. Research involving pregnant women, fetuses, and neonates is generally expected to hold out the prospect of direct benefit. If no such prospect of direct benefit is available, then the risk must be minimal and the purpose of the research must be the development of important biomedical knowledge that cannot be obtained by any other means. For pregnant women and fetuses, any risks associated with the research will be the least possible for achieving the objectives of the research. For neonates, no risks may be added as a result of the research. Researchers will not: (1) offer any form of inducement to terminate a pregnancy; (2) determine the timing, method, or procedure used to terminate a pregnancy; or (3) determine the viability of a neonate. Researchers conducting studies with these populations must follow sound ethical principles and follow all appropriate provisions regarding informed consent.

STUDIES INVOLVING DECEPTION

Deception is the intentional misleading of subjects or the withholding of full information about the nature of the study. Investigators may mislead or omit information about the purpose of the research, the role of the researcher, or what procedures in the study are actually experimental. Deception increases ethical concerns because it interferes with the ability of the subject to give informed consent. Deception may be necessary in certain types of research so that results are not biased. The use of deception or incomplete disclosures can only be approved if the following conditions are met:

- Other than deception, other risks to the subjects are not more than minimal;

- The research could not practicably be carried out without the waiver or alteration;
- If the consent process must be altered or waived, the rights and welfare of the subjects will not be adversely affected; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation. This debriefing may include
 - a description of the deception,
 - the necessity of the deception as it relates to the purpose of the research, and
 - an option for participants to withdraw their data from the study after they learn the true nature of the research, particularly if it is of a sensitive nature.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA)

Research that involves health and health-related information may be subject to the privacy standards for protected health information as established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Researchers who gather health-related data and are responsible for the storage and destruction of such data are expected to comply with HIPAA guidelines as well as all other required privacy standards.

INITIAL REVIEW OF RESEARCH

Submission of Application

Applications and instructions for each level of review are on the IRB webpage at <https://www.twu.edu/institutional-review-board-irb/>. The separate instructions include submission requirements in addition to instructions for completing the application. Applications are entered into the IRB database by IRB staff at the time they are received and are tracked in the database until they are closed.

Applications submitted by faculty PIs require approval from the academic unit administrator. The faculty member certifies that he/she accepts primary responsibility for all aspects of the research project. The academic unit administrator certifies that he/she has read, reviewed, and approved the content of the application.

Applications submitted by students require approval from the faculty advisor and the academic unit administrator. The student certifies that he/she accepts primary responsibility for all aspects of the research project. The faculty advisor and academic unit administrator certify that they have read, reviewed, and approved the application. Incomplete applications or applications containing unclear information may delay the review and approval process.

IRB submission forms are revised as necessary to improve the process or to meet University and Federal regulations. Revisions are approved by the IRBs prior to implementation.

Possible Actions

The IRB may take one of three actions regarding proposed protocols: approve, request changes, or disapprove.

- **Approve:** Permission has been granted to proceed with the research as proposed.
- **Request changes:** Specific changes must be made before the protocols can be approved. The IRB determines whether required changes will be reviewed by the IRB, an *ad hoc* committee of the IRB (i.e., the Chair and two other IRB members), or the Chair. Investigators are notified of required revisions immediately following the review of the study. The notification includes specific instructions for implementing and documenting the required changes. Required revisions must be received by the IRB within six months of the notification or the protocol file will be closed.
- **Disapprove:** The IRB has determined that the rights and welfare of research participants cannot be adequately protected as the protocol is designed. Decisions for disapproval go to the full IRB for consideration. The IRB shall notify investigators and the institution in writing of its decision to disapprove proposed research activity. The written notification shall include a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

Approved Protocols

Notification letters signed by the IRB Chair (or Co-Chair in the absence of the Chair) are sent to PIs when protocols have been approved.

Copies of the approval letter are sent to:

- PIs;
- PI's Department;
- Faculty advisors when PIs are students; and
- Graduate School, when PIs are graduate students.

Copies of IRB approval letters may be required with external funding proposals involving research with human subjects.

Researchers must submit copies of signed consent forms to the IRB upon completion of projects or be granted an exception by the IRB for this requirement. Original signed consent forms should be retained by the investigator. Consent forms placed on file with the IRB will be handled with the confidentiality of the subjects in mind.

Graduate students who have conducted research as required by degree plans will be cleared to graduate only when all signed documents are received by the IRB and the Graduate School has been notified.

Disapproved Protocols

PIs are notified in writing by the Chair when protocols have been disapproved by the IRB. The IRB will work closely with PIs to modify aspects of protocols that are cause for concern. PIs may resubmit protocols that incorporate the required changes. PIs may appeal decisions of the IRB by submitting a brief summary outlining the reasons for the appeal. PIs who appeal decisions must attend the convened IRB meeting in which the appeal is reviewed.

INTERIM REVIEW PROCEDURES

Review of Proposed Changes in Research Projects (Modifications)

Researchers are required to promptly report proposed changes in research activities to the IRB. Such changes during the period for which IRB approval has already been given may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the participant. The requirement for prompt reporting is stated in both the initial approval letter and the extension letter, is included in IRB training, and is stated on the IRB website.

Researchers must complete the *IRB Modification Request Form* found on the IRB website at <https://www.twu.edu/institutional-review-board-irb/> to propose changes in a research activity. Changes to previously approved and exempted research are reviewed by the IRB Chair or by one or more experienced reviewers designated by the Chair from among members of the IRB. Except in the instance of a change of principal investigator, modifications for the sole purpose of adding or removing a research team member(s) may be administratively reviewed and processed by the IRB staff. In reviewing the request for modifications, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. These authorities include referral to a convened IRB meeting if more than minimal risks are involved (*46 CFR part 103(b)(4)*). When a modification to an exempt study is approved, the closed date of the protocol will be changed to reflect the date of the most recent modification.

Continuing Review of Research (Extensions)

Continuing review of research is required for all expedited and full review studies and will be conducted at intervals appropriate to the degree of risk, but not less than once per year. Extension requests must be reviewed prior to the anniversary date of the last approval. Full review anniversaries are the date of the full IRB approval. The IRB may determine the frequency of continuing review of protocols based on an investigator's IRB history including past and current violations, the level of risk, the vulnerability of the participant population, the use of deception, the complexity of the project, or any other concern. The IRB may take the same actions on continuing reviews as those taken on initial applications. Investigators are notified of required revisions to an extension request immediately following the review of the request.

PIs are notified of renewal dates and the requirement to submit requests for extensions or requests to close IRB files at least 30 days prior to the anniversary date of the last approval. Extension requests on full review studies are reviewed at fully convened IRB meetings and

therefore should be submitted both prior to the expiration and prior to the next scheduled IRB meeting. IRB meeting schedules are on the IRB website at <https://www.twu.edu/institutional-review-board-irb/>. Extension requests for expedited studies and studies where subject enrollment and data collection are complete may be reviewed by the IRB chair or co-chair.

Extension requests must include the number of participants accrued, a summary of unanticipated problems and/or adverse events, participant complaints, withdrawals, and a summary of amendments and modifications since the last review. Current consent documents must be attached to the extension (see *Minor Noncompliance* for procedures on lapses of IRB approval).

CLOSEOUT OF IRB PROTOCOL

Studies exempted prior to September 1, 2018, were closed at the time that the exemption was issued. Studies exempted after August 31, 2018, will not be closed. Instead, a status report will be requested every two years. The file will remain active until the PI files a *Close Study Request Form* or does not respond to the status report request.

Investigators who have received approval for an expedited or full-review study must submit a request to close their file when approved research projects are completed. A *Close Study Request Form* should be submitted prior to the expiration date of the study. A protocol file must also be closed when the investigator is no longer at the University unless a modification is approved to change the investigator on a study. Any exception allowing an investigator no longer affiliated with TWU to maintain an active IRB approval must be approved by the appropriate Dean and Vice Provost for Research. The *Close Study Request Form* must include the number of participants accrued, a summary of unanticipated problems and/or adverse events, participant complaints, withdrawals, and a summary of amendments and modifications since the last review.

Researchers must submit copies of signed consent forms to the IRB upon completion of projects or be granted an exception by the IRB for this requirement. Original signed consent forms should be retained by the investigator. Consent forms placed on file with the IRB will be handled with the confidentiality of the subjects in mind.

Graduate students who have conducted research as required by degree plans will be cleared to graduate when all signed documents are received by the IRB and the Graduate School has been notified.

IRB RECORDS

The IRB will prepare and maintain adequate documentation of IRB activities, including the following.

- Copies of all research proposals reviewed, scientific evaluations that accompany proposals, approved informed consent documents, progress reports, and reports of adverse events / unanticipated problems;

- Minutes of IRB meetings in sufficient detail to show attendance at the meetings; actions taken by the IRB; votes on these actions including the number of members voting for, against, and abstaining; the basis for required changes in or disapproval of research; and summaries of the discussion of controverted issues and their resolution;
- Records of continuing review activities;
- Copies of all correspondence between the IRB and the investigators;
- List of IRB members and copies of their vitas;
- Written procedures for the IRB; and
- Statements of significant new findings provided to participants.

The records maintained by the IRB will be retained for at least three years from the file closed date. All records will be accessible for inspection and duplication by authorized representatives of the DHHS at reasonable times and in a reasonable manner.