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SMU IRB Researcher Handbook

Purpose of Handbook
The purpose of this document is to provide guidance to researchers at SMU who want to perform research on human subjects. This document provides information about the federal regulations as well as SMU policies supporting and interpreting the regulations.

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CITI Training
For training, go to
https://www.citiprogram.org/
from a SMU networked computer

Code of Federal Regulations
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

Visit SMU Research Compliance website for the following documents:

Blank Forms
Consent Form Template
Consent Process Alteration
Problem Report
Continuing Review
Amendment
Lapse in IRB Approval
International Research
Exempt Status Determination

Sample Forms
Consent and Application for Socio/Behavioral Research
Consent and Application for Physiological Research
Consent and Application for Qualitative Research
Role and Authority of the IRB

The main role of the IRB is to ensure that the rights and welfare of research participants are protected. This is done through the approval of all human subjects research and continued monitoring of previously approved studies.

Authority of the IRB

- “An IRB shall review and have the authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy.” (45 CFR 46.109 (a))
- “An IRB shall conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but no less than once per year, and shall have the authority to observe or have a third party observe the consent process.” (45 CFR 46.109 (e))
- “Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval and disapproval by officials of the institution. However, those officials may not approve the research if it has not been approved by an IRB.” (45 CFR 46.112)
- “An IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB’s requirements or that has been associated with unexpected serious harm to subjects.” (45 CFR 46.113)

Foundations of the IRB and Human Subjects Research

The Belmont Report (1978) provides the foundation for the three basic ethical principles for conducting human subjects research:

- **Respect for persons:** Research participants should understand as completely as possible what is to be done to them, what information will be gathered about them, and what the potential risks and benefits are if participating in a research study. The participant must give his/her consent freely, without pressure or inappropriate inducement. This is indicated by voluntary and informed consent.

- **Beneficence:** The IRB is charged with deciding whether risks to a participant are outweighed by the combination of potential benefits to the individual subject and the importance of the knowledge to be gained from the study. In other words, an appropriate balance must exist between potential benefits of the research to the subject and/or to society and the risks assumed by the subject.
• **Justice:** There must be fair procedures and outcomes in the selection of research subjects and the risks and potential benefits should be evenly spread.

**Federally Mandated for Humans Subjects Research**

The Department of Health and Human Services (DDHS) provides federal regulations (Title 45, Part 46 of the Code of Federal Regulations) or what is referred to as the Common Rule to provide guidance for human subjects research. Any institution receiving federal funding is required to adhere to the Common Rule. ALL human subjects research at SMU must be evaluated by the IRB for approval and monitored throughout the research regardless of funding sources.

**Key Events in the Development of Human Subjects Research Regulations:**

- **The Nuremberg Code (1948):** The Nuremberg Code was established as a result of the trials against Nazi physicians and administrators for experiments conducted on concentration camp women, men, and children. The Nuremberg Code led to guidelines such as the requirement that subjects freely consent to participate in research, ensuring ability of people to consent, and the idea of the risk vs benefit ratio, qualification of researchers, and ability of participants to withdraw consent.

- **“Declaration of Helsinki” (1964):** This declaration established recommendations for doctors and biomedical research involving human participants.

- **“Ethics and Clinical Research” in the New England Journal of Medicine (1966):** Henry Beecher provided 22 examples of medical research in the United States in which researchers had not told research subjects about the nature of their participation, did not have informed consent, and put their health at risk.

- **Tuskegee Syphilis Study (1932-1972):** Conducted with Public Health Service funding, this study included 400 rural black men in Alabama with Syphilis who were deliberately left untreated – even after effective antibiotics became available – so that the natural progression of Syphilis could be studied.

- **The National Commission of 1974:** Legislation was enacted that established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission’s principal charge was to review the practices and problems associated with the protection of the human subjects in research sponsored by the federal government.
• The Belmont Report (1979): Issued by the National Commission, the Belmont Report outlines “basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects.” Two years later, the U.S. Department of Health and Human Services (45 CFR 46) and the Food and Drug Administration (21 CFR, parts 50 and 56) issued regulations requiring the establishment of IRBs to ensure compliance with the ethical principles outlined in the Belmont Report.

• Continued Research Scandals: The press has begun to scrutinize human research at major research institutions. Several institutions have had all or some of their human research approvals suspended – some for several months – until they could bring their human subjects protection programs up to federal standards. (e.g., Duke University, Coast IRB sting, UC Davis)

Composition of the IRB

**IRB Members:** Federal regulations require that membership of the IRB have at least five members with varying backgrounds. The composition must include, at a minimum: one member whose primary concerns are scientific areas, one member whose primary concerns are nonscientific areas, and at least one member not affiliated with SMU. However, it is the goal to have the SMU IRB to reflect the diverse community of researchers at SMU to adequately review and monitor the research activities at SMU. The Associate Vice President for Research will appoint members to the IRB after consulting with the Director of Research Compliance and IRB Chair. The IRB members will serve a two-year, renewable term.

**IRB Chair:** The chair of the IRB is appointed by the Associate Vice President for Research. The chair will be appointed from the tenured faculty at SMU. The chair will serve a two-year, renewable term.

Director of Research Compliance (DRC): The DRC serves as an ex officio (i.e., non-voting) member at the full-board meetings and in an advisory role.

**Special Consultants:** On rare occasions, the IRB Chair may invite an expert to consult on a specific protocol if the IRB committee votes that someone is warranted. This expert is not meant to be a replacement for departments at SMU having representation on the board. Rather, an expert may be utilized if no IRB member is knowledgeable about a specific issue or experienced in working with a specific area such as a new, specialized technology. Consultants will be sought based on their expertise and the expert may not have a conflict of interest (e.g., see SMU’s policy on conflict of interest).
Consultants will serve only in an advisory role and will not be allowed to vote.

Definitions

Research

Federal Regulations define research as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45CFR46.102(d)). As described in the Belmont Report, “…the term ‘research’ designates an activity designed to test a hypothesis [and] permit conclusions to be drawn... Research is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.”

Human Subjects

A human subject is defined by Federal Regulations as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” (45 CFR 46.102(f)(1),(2))

**Intervention:** Physical procedures, manipulations of the subject, or manipulations of the subject’s environment for research purposes.

**Interaction:** Communication between the investigator and the subject. This includes face-to-face, mail, email, and phone interaction as well as other modes of communication.

**Identifiable private information:** “Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place;” (such as a public restroom) “and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a health care record).” (45 CFR 46.102(f)(2))

**Identifiable:** Information contains one or more data elements that can be combined with other reasonably available information to identify an individual (e.g., birth date, SSN, email address, etc.) NOTE: Do not assume information qualifies as “publicly available” just because it has been posted on an electronic website and can be accessed without authorization.
IRB

“IRB means an institutional review board established in accord with and for the purposes expressed in this policy.” (45 CFR 46.102(g))

IRB Approval

“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.” (45 CFR 46.102(h))

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.” (45 CFR 46.102(i))

Directly Identifiable Data

Data that are labeled with unique identifiers that allow the identity of the subject to be ascertained by the investigator associated with the information.

Indirectly Identifiable Data

Data that have a code or key to identifiable information about a participant.

Non-Identifiable Data

Data that cannot be linked to a specific participant because either it was never linked to a code or the data is received after the key or code has been removed/destroyed.

Conflict of Interest

If a member of the research team could personally benefit (e.g., financially) such that it could influence judgment. A conflict of interest does not imply that a researcher’s judgment has been compromised; rather, there is the potential for a conflict of interest. Please refer to SMUs conflict of interest policies and procedures for more information.
Confidentiality
Only the investigators or individuals on the research team can identify information from individual participants. This could be a name, but include something like an email, date of birth, or address.

Generalized Knowledge
Scholarly work that is intended to have an impact on others within one’s discipline. Examples could include: journals, conferences, books, blogs, online repositories, non-peer reviewed format with the intent of sharing, etc.

Anonymity
No identifying information (e.g., name, email, address, date of birth, etc.) is collected from participants, nothing can be linked to a specific participant, and researchers have not interacted with participants.

The Principal Investigator and Responsibilities
Principal Investigator (PI): The individual who assumes full responsibility for the research project, and who is ultimately responsible for ensuring the research stays in compliance with federal regulations and SMU policies by:
- Obtaining IRB approval before beginning human subjects research
- Assuring the design is appropriate for the research questions
- Protecting the rights of participants
- Ensuring procedures do not unnecessarily expose participants to risk
- Verifying that all research team members are listed on the protocol and have completed CITI training
- Ensuring research team members follow the approved protocol
- Seeking approval for any changes in methodology or the protocol before any new changes are implemented
- Contacting the IRB if any incidents arise that harm or the potential for harm of participants in the research (use critical incident form)
- Seeking a Continuing Review if the research goes beyond the initial one year approval (submit continuing review form 2 months before permission expires).
- Notifying the IRB when the research is completed
Who MAY be a PI at SMU:

- Any tenured and tenure-track SMU faculty and SMU librarians who have completed CITI training.
- All SMU personnel who have a Research title and function at SMU who have completed CITI training.
- Any instructor, visiting professor, clinical professor, professor of the practice who has approval from the Department Chair or Dean and have completed CITI training.
- SMU staff members who feel comfortable that they understand the research process and management of this process AND have the approval from the Dean or Appropriate Representative and have completed CITI training. If a SMU staff member is not comfortable, he/she may contact the IRB who can help provide them with a mentor or extra training.
- Any doctoral graduate student past their first semester of graduate school who have completed CITI training.

Who may NOT be a PI at SMU:

- Anyone who has not completed CITI training.
- Undergraduate students must have a faculty advisor as the PI.
- Master's level graduate students must have a faculty advisor as the PI.
- Anyone not a part of the SMU community

Other Research Members and Responsibilities

Co-Investigators: Key personnel who are responsible for:

- Being familiar with and employing approved protocol procedures for the study
- Ensuring participants have given informed, voluntary consent to participate in the study
- Seeking permission from PI before deviating from approved procedures
- Maintaining current CITI training (good for 3 years)
- Notifying the PI if any incidents arise that harm or the potential for harm of participants in the research
- Treating participants with dignity and respect
Types of Review

Exempt Review: Unfortunately, there are often few specific regulations to determine if a study is exempt or not. However, it is the responsibility of the IRB to make fair and consistent decisions as to what studies will be exempt at SMU. Further, the IRB determines exempt status NOT the researcher. All human subjects research MUST be submitted to the IRB for evaluation. Exempt does NOT mean “no review”.

To even be considered for exempt status, two criteria must initially be met:
1. This research must involve no more than minimal risk.
2. The research may not involve children, prisoners, individuals who are mentally disabled, and pregnant women.

If the above criteria are met, then the research must fit into one of the following six categories that does not collect any identifiers.

1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
   • Research on regular and special education instructional strategies, OR
   • 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:
   • The information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; AND
   • Any disclosure of the human participants’ responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants’ 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 Category B2, if:
   • The human participants are elected or appointed public officials or candidates for public office, or
   • 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 participants cannot be identified directly or through identifiers linked to the participants.

5) Research and demonstration projects which are conducted by or subject to the approval of appropriate Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:
- Public benefit or service programs; or
- Procedures for obtaining benefits or services under those programs; or
- Possible changes in or alternatives to those programs or procedures; or
- Possible changes in methods or levels of payment for benefits or services under those programs.

6) Taste and food quality evaluation and consumer acceptance studies,
- If wholesome foods without additives are consumed, OR
- 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. (45 CFR 46.101)

**Expedited Review**

Expedited reviews are completed on research that poses only minimal risk to participants. In the case of expedited reviews, the proposal will not be reviewed by the full board and can be handled throughout the year.

The Code of Federal Regulations (45 CFR 46.110) permits research activities in the following seven categories to undergo expedited review:

1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. *(Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)*
   b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2) Collection of blood samples by finger stick, heal stick, ear stick, or venipuncture as follows:

- From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

- From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3) Prospective collection of biological specimens for research purposes by noninvasive means.

**Examples:**

- Hair and nail clippings in a nondisfiguring manner;
- Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
- Permanent teeth if routine patient care indicates a need for extraction;
- Excreta and external secretions (including sweat);
- Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
- Placenta removed at delivery;
- Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
- Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
- Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
- Sputum collected after saline mist nebulization.

4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical
device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

**Examples:**

- Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
- Weighing or testing sensory acuity;
- Magnetic resonance imaging;
- Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electoretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
- Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

6) Collection of data from voice, video, digital, or image recordings made for research purposes.

7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

**Full-Board Review**

Research that does not qualify for expedited or exempt review and/or presents more than minimal risks to subjects shall be reviewed at a fully-convened board meeting.

**Below are some examples of situations at SMU likely to require full board review:**

- The proposed research involves vulnerable populations.
- The proposed research includes video or audio recordings or photos where identification of the subjects could place them at risk such as legal, employability, reputation, etc.
- The researcher is seeking a waiver or alteration of informed consent.
• The proposed research involves deception.
• The research involves physically invasive procedures.

**IRB Process**

Prior approval must be sought before research is conducted on human subjects. Any research completed without IRB approval may not be used in public presentations or publications including but not limited to: journals, books, websites, blogs, etc.

**Application:** Researchers must submit a complete research plan with accompanying documents (e.g., consent forms, surveys, questions, scripts, recruiting material, etc.) to be reviewed to the Director of Research Compliance (DRC). To do this, researchers will complete an application found on the SMU IRB website and provide all supporting documents to the Director of Research Compliance.

**Review Process:**

• The DRC, will review the application for completeness and request any needed information from the researchers.
• This process may take several resubmissions by the researcher before a packet is ready to send to the IRB Chair.
• The DRC will send application materials to the IRB Chair who will determine the type of review needed: Exempt, Expedited, or Full-board.

**If the study is Exempt:** These studies are reviewed throughout the calendar year. The DRC and IRB chair will make a determination if the study meets the criteria of exempt status. If yes, an official letter will be sent to the researcher stating that the study is exempt. No research may be conducted until the exempt IRB letter is sent.

**If the study is Expedited:** These studies are reviewed throughout the calendar year. At least one member of the IRB will review the file and provide the researcher with a letter requesting any modifications. The researcher will make the necessary changes or explanations as to why the change is not feasible. The new materials are submitted to the DRC and passed to the same IRB member who initially reviewed the study. This process will continue until all necessary changes are made to the study procedures. Once the protocol is approved, the researcher will be sent a letter stating they have approval for the research and how long the approval is good – typically one year. No research may be conducted until the IRB final approval is sent.
If the Study is Full-Board: These studies are reviewed at the monthly IRB meeting. A list of the meeting dates and required date for materials to be submitted is on the IRB website. All members of the IRB committee will receive a copy of the study to review. The researcher will be invited to attend the monthly IRB meeting to present their research and answer clarification questions from the IRB committee. After the meeting, the researcher will be sent a letter requesting any needed modifications. Once the requested modifications have been addressed, the researcher will submit the application material to the DRC. Depending on the extent of the required modifications, the researcher may or may not be required to come back before the full board. This process will continue until all necessary changes are made to the study procedures. Once the protocol is approved, the researcher will be sent a letter stating they have approval for the research and how long the approval is good – typically one year. No research may be conducted until the IRB final approval is sent.

Criteria Used to Evaluate IRB Proposals:

- Have the risks to participants been mitigated, or minimized?
- Are the anticipated and potential risks reasonably balanced to the anticipated benefits of the research?
- Are the recruiting and selection processes of subjects fair/equitable (e.g., free from bias and not unintentionally targeting special groups)?
- Is the consent process such that participants can make an informed and voluntary decision to participate (e.g., understandable language, accurately reflect what to expect, anticipated risks, rights, not coerced, etc.)?
- Are the data protected to assure the privacy and well-being of participants?

Possible Outcomes:

Approved: No further action is required from the PI and the research may be started. Researchers are NOT allowed to begin research until a letter has been received from the IRB stating the study has been approved.

Approval Pending Modifications: Minor changes are needed to the protocol before research on the study may begin.

Denied: The proposed research cannot be conducted as proposed due to the level of risk involved. If this happens, the IRB will work with the researcher to find a way to conduct research if possible.
Types of Risk

Examining risk is one of the main foci of the IRB when reviewing and application. It is important to note that it is extremely common for research studies to have some risk.

**No greater than minimal risk:** This is where the risk of psychological, physical, social, legal, etc. is no greater than what would be ordinarily encountered in daily life or during the performance of routine physical or psychological examinations (45 CFR 46.102(i)).

**Greater than minimal risk:** When the risk of psychological, physical, social, legal, etc. exceeds what would be ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.

- **Emotional Risk:** Any research activity such as a survey, questionnaire, viewing of stimuli, or experimental condition that could possibly result in emotional stress.
- **Privacy/Confidentiality Risk:** Any research activity which could result in negative consequences for participants if their confidentiality is broken.
- **Physical Risk:** Any research activity where a participant could be physically harmed.
- **Legal Risk:** Any research activity where illegal activity or information may be uncovered.
- **Economic Risk:** Any research activity where the participant incurs costs or where it could affect a participant’s livelihood.
- **Social Risk:** Any research activity that could harm a participants standing in the community or cause them to lose their job.

Vulnerable Subjects

SMU’s IRB takes a strong stance when it comes to vulnerable populations and their protection. Federal regulations require IRBs to give additional protection to the defined categories of vulnerable subjects (45 CFR 46 Subparts B-D). However, the guidelines suggest in addition to children, prisoners and pregnant women, people with a impaired cognitive ability, or economically and educationally disadvantaged people may be considered as vulnerable populations.

SMU’s IRB also considers prisoners, pregnant women, and people with impaired cognitive ability vulnerable populations. Individuals with impaired consent capacity include individuals who may be unable to legally provide informed consent related to some
impairment. This could include individuals with a severe mental illness (e.g., psychoses, schizophrenia, severe depression, etc), developmental disabilities, dementia, traumatic brain injury and anything where there is a reduced cognitive capacity. For the additional groups mentioned in the regulations, the IRB will look at the context of the study to determine whether these additional groups are vulnerable based on the context. In addition, we look at additional populations that would normally not be considered vulnerable, but the context of study could make them vulnerable. A vulnerable population does not necessarily trigger a full-board review, although it often will.

**Recruiting of Research Subjects**

The IRB shall review all materials used to recruit research subjects. Advertisements should include:

- Name, office address and phone number of the appropriate person to contact for additional information;
- The location of the research;
- Wording that effectively communicates the purpose of the research;
- The eligibility criteria to be used in selecting participants/subjects;
- A truthful description of the benefits;
- if subjects be compensated;
- and the duration of the project.

In addition, advertisements should not provide misleading, inaccurate, or coercive information. For instance, if participants will receive payment for participating, this should not be the focus of the flyer.

**Equitable Selection of Participants**

It is the responsibility of the IRB to ensure equitable selection of participants. To do this, the IRB will review inclusion/exclusion criteria for the research study and take into account the purpose of the research, the context of the research, as well as the vulnerability of the participants.

**Coercion or Undue Influence**

- **Dual Relationships:** A dual relationship concern can exist when the researcher or recruiter for the study is in a position of power or influence over the research participants not connected to the research. For example, a doctor suggesting a patient participate in a research study may result in a patient thinking they have to participate in the research. Another example would be a professor
in a class recruiting participants for research and the students feeling they could have a grade lowered or have a negative impression by the professor if they do not participate.

- **Remuneration:** Remuneration to participants must be perceived as being proportional to the risks and time related to the study. For example, a large amount of money might overly influence a person who is homeless to participate in a research study.

**Remuneration to Participants**

Remuneration to participants may be used as an incentive to recruit participants for the research study or to reimburse participants for their time, travel, or expenses to participate. However, researchers must avoid remunerations that could be seen as coercive or having undue influence to potential participants. In other words, compensation must be perceived as being proportional to the risks and time related to the study. The IRB must approve both the amount and disbursement of remuneration to assure there is no undue influence or possible coercion from the remuneration. In addition, the consent document must describe the amount of remuneration, terms to receive the remuneration (e.g., if partial payment if they withdraw before the study is completed or if they get paid after each research session, etc.). Typically payment should not accrue if there are multiple parts to the study. If identifying information is needed from the participants to receive remuneration, then this must be explained to the participants in the consent.

**Protocol Materials that IRB Must Review**

The IRB shall review all materials to be presented to (seen or heard) participants participating in research projects. This includes materials, but not limited to, such as recruiting flyers, emails, phone scripts, experimental manipulations, questionnaires, videos, information sheets, debriefing materials, etc. All such materials will be submitted to the Director of Research Compliance along with the other documents required for initial review. These materials will be reviewed for their appropriateness and protection of the study participants by the IRB.

**Informed Consent**

Informed consent is voluntary agreement to participate in research. Consent is not a document; informed consent is a process that engages research personnel with potential study participants. (This also suggests that participants may need to have additional information throughout the study to ensure continued informed consent.) The goal of informed
consent is to provide enough information so participants can make an informed decision about participating in the study or not.

- The language of the consent must be in a language easily understood by the participants.
- No coercive language should be used (e.g., you must, your doctor suggested you participate, etc.).
- The legal rights of participants cannot be waived and participants may not release SMU, researchers, sponsors from any liability nor the use of exculpatory language.
- It is the researcher’s duty to make sure participates understand what is being asked of them and that participants are freely choosing to participate in a study.
- Investigators must be able to identify participants if the IRB feels that it is necessary in cases where there are crucial eligibility criteria for higher risk studies or studies electing to use photos or videotaping.
- The final approved consent form must have the IRB stamp of approval on it and may not be modified without permission from the IRB.

**Essential Elements of Consent**

At a minimum, subjects must be provided the following information during the consent process:

- Purpose of the research
- Procedures involved in the research
- Alternatives to participation (if appropriate)
- All foreseeable risks and discomforts to the subject. Note: that these include not only physical injury but also possible psychological, social, or economic harm, discomfort, or inconvenience.
- Benefits of the research to society and possibly to the individual human subject
- Length of time the subject is expected to participate
- Person to contact for answers to questions or in the event of a research-related injury or emergency
- IRB/compliance informatoin
- Statement indicating that participation is voluntary and that refusal to participate will not result in any consequences or any loss of benefits that the subject is otherwise entitled to receive
- Statement regarding the subjects’ right to confidentiality and right to withdraw from the study at any time without any consequences
• Often additional information will be needed such as payment, costs to participate, how findings will be presented, number of subjects, etc.

Special Considerations Regarding Informed Consent

There are some special situations that may affect the informed consent process. We have listed examples below and what must be considered differently in these cases - other circumstances may also require additional considerations.

Web Consent: A consent form must be presented to participants before the study starts. A box may be checked by participants in lieu of a signature with a statement that they understand and agree to participate. Electronic signatures may also be used if the signature can be shown to be legitimate, and if the consent or permission document can be produced in hard copy for review by the potential subject.

Non-English Speaking Participants: If the majority of participants are non-English speakers or are not comfortable with English, then the participants MUST be consented in their native language. In this scenario, the IRB will approve an English version of the consent. Before final approval is given to the PI, the translated versions of the consents must be submitted to the IRB. These translations must be done by someone fluent both in speaking and writing of the language. It is the responsibility of the PI to provide a short justification with the translated versions ensuring that the translations are accurate, to the best of their knowledge.

Children/Adolescents: If children or adolescents are involved in the research study, additional steps are needed for informed consent. Minors under the age of 18 (there are some exceptions) may not provide legal permission to participate in research. In these cases, parental or guardian permission is necessary. If the study is considered high risk, permission from both parents may be required. In addition, if the children are between the ages of 8 and 17, written or verbal assent must be sought from the children. Assent is an active affirmation of wanting to participate in the research from someone not legally able to provide consent. The assent process is used to make sure children understand the research and what it means to participate.

Passive or Implied Consent: Assume that consent has been given unless some action is taken. Passive or implied consent is not equivalent to informed consent. Examples of passive consent include enrollment in an educational study unless the student returns the consent document
opting out of participation or responding to a survey by which mailing the documents back to the researcher automatically enrolls one in the study. The use passive or implied consent methods requires IRB approval to alter some or all of the informed consent process.

**Adults with Guardians:** When adults lack the capacity/legal authority to provide consent (e.g., cognitively impaired, developmentally delayed, dementia, psychoses, brain damaged, etc.), consent must be obtained from their legal guardian. The IRB may also request that assent is sought from the participant. Assent is an active affirmation of wanting to participate in the research from someone not legally able to provide consent. The assent process is used to make sure the adults still understand the research, what it means to participate, and if they want to participate.

**Waiver of Elements of Consent:** Waiver of one or more elements of the consent may be obtained from the IRB for some research projects that could not practically be done without an alteration to the required elements (e.g., a study involving deception) or for studies where required elements are not applicable. These waivers are reviewed on a case-by-case basis and must be thoroughly explained in the application.

**Waiver of Signature on Consent:** Waiver of signature of informed consent may be obtained if documentation of the consent is the only link to a study in which a participant could be compromised AND the principle risk would be potential harm resulting from a breach of confidentiality (e.g., prostitutes, drug users, etc). Other potential reasons may be for cultural reasons such as a high illiteracy rate. If there are emails, phone numbers, or other documented ways to follow-up, then the signature of consent will typically not be waived. Waivers are reviewed on a case-by-case basis and the rationale for the waiver must be thoroughly explained in the application. Ease of the study is NOT a valid reason. Nor is the rationale that participants would not want to be in the study if they knew what was going to be asked of them a reason to grant waiver of consent. Even if a waiver is granted, this does not mean participants do not have to be consented.

**Deception Research:** The use of deception may be used when researchers need to investigate questions that could be confounded by the participants knowing the complete research story. There are degrees of deception from using a vague research statement in the consent process to a complete fabrication of the research purpose in the consent process. It is the IRB's task to weigh the risk created from type and degree of
deception against the overall goals of the study. Typically, if deception is used, the IRB will require a debrief document (either electronic or paper) to be given to the participants at either the completion of their participation or conclusion of the study. This document/process explains the true purpose of the research. It is the researcher’s job to clearly explain the need for deception and how it outweighs the risk to participants in the risk/benefit section of the protocol.

**Photo/Audio/Video Recording:** May be appropriate methods to be used in research studies. However, the rationale for the use of these techniques must be documented in the protocol. Because these methods are used in a specific domain of study is not an acceptable rationale; the rationale should include why these methods are necessary to the specific study. In addition, the consent document must be clear that these methods will be used and participants must give their explicit consent. This can be accomplished within the consent document or a separate document may be used.

**Public versus Private Behavior:** Methods to collect data related to private behavior requires informed consent.

**Reporting Critical Incidents, Unanticipated Problems, or Adverse Events**

Federal regulations (CFR46.103(b)(5)) require the IRB to insure that investigators promptly report “any unanticipated problems in involving risk to subjects or others.” If there are unanticipated problems involving risk to participants or complaints about the research, researchers must notify the Chair of the IRB and DRC within 24 hours of the incident at researchcompliance@smu.edu.

A Problem Report must be completed and filed with the IRB within seven days of the incident. The reporting of these incidents is critical to ensure that steps are taken quickly to ensure that steps are taken to protect other participants from harm that could be prevented. These regulations also require unanticipated problems and adverse events to be reported to federal agencies (i.e. OHRP, NSF, NIH) by the IRB.

**Unanticipated Problems include any incident or outcome that meets all of the following criteria:**

**Unexpected** (in terms of nature, severity, or frequency)

Related or possibly related to participation in the research possibly related means there is a reasonable possibility that the incident, experience,
or outcome may have been caused by the procedures involved in the research); and suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

**Adverse Events** encompass all types of harm such as physical, emotional, social, economic, legal, and confidentiality. Adverse events may be caused by: procedures involved in the research; an underlying disorder, condition, or disease of the participant; other circumstances not related to the procedures or underlying conditions.

**Other Types of Events to be Reported**
- Unanticipated changes to protocol to eliminate an immediate risk to a participant.
- Any event that affects the safety or welfare of participants.
- New information that could indicate an unexpected change in the risk/benefit profile (e.g., new publication or research, etc.)
- Complaints of participants

**Examples of corrective actions**
- Changes to the protocol
- Modification of inclusion/exclusion criteria
- Modifications to informed consent to document risks
- Letter to enrolled participants describing new risks
- Require re-consenting of participants
- Additional monitoring requirements
- Suspension of enrolment of new participants
- Suspension of the research study
- Require training of the research team

**Changes of the Protocol/Amendments**

Any changes in the previously approved protocol must be approved by the IRB. This includes changes to the consent form, recruitment of participants, assessment information, surveys, study procedures, research personnel, etc. An amendment form must be completed and approved by the IRB before any changes can be implemented. It is the responsibility of the PI to ensure that research staff conforms to the approved protocol during the study.
Continuing Review

Approval given by the IRB for human subjects research is good for one calendar year (12 months) or less. (If research involves extreme risk for participants, approval may be given for a lesser time period.) If the approved study extends beyond the initial approval period, the PI must seek approval again. This process is completed by filling out the Continuing Review Form, which provides an update on the progress of the study. This should be submitted two months before the research approval runs out to ensure approval is granted before the initial approval runs out. Continuing reviews must be submitted until all enrollment and analysis on all identified data is complete.

Closing Out a Research Protocol

It is the responsibility of the PI to inform the IRB once all research activities related to a specific protocol are completed. To do this, the PI will complete one last Continuing Review provide an update since the last continuing review and indicate that all research activity has ended.

Retention of Records and Destruction of Data

Once a research study is completed, data must be maintained for a specific amount of time. Federal IRB regulations require research records to be retained for at least 3 years after the completion of the research (45 CFR 46.115). However, other regulations or agencies may require data to be retained for a longer period of time. The records must be kept for the longest period of time.

Human Subjects Protections Training/CITI Training

All SMU research personnel who interact with human subjects or work with identifiable human subjects data must complete CITI training. In addition, any personnel outside of SMU (other institutions, organizations, sub-contractors, etc.) must complete CITI training or an equivalent (approved by IRB) and have it filed with the IRB. Furthermore, the names of these people must be provided to the IRB on the initial protocol. If additional research staff is added as the project progresses, an amendment must be filed with the IRB with this information. It is the responsibility of the PI to ensure that all staff has the correct training on file with the IRB. CITI training is good for 3 years and then must be renewed.
Secondary Data

Secondary use of data applies to activities that involve secondary analysis or using existing data such as data collected from previous studies, data originally collected for a different purpose, audio/video recordings from other studies, student records, etc. In other words, the data in question has already been collected.

Even though secondary data sources may appear to not involve any interactions or interventions with human subjects (see definition of human subjects 45 CFR 46.102(f)), this data may still be classified as human subjects research. If the data was obtained from living human subjects and some type of identifiable private information was collected, this data may still constitute human subjects research.

As with any other human subjects research, whether secondary data is considered exempt or not must be determined by the IRB and not researchers.

Examples of secondary data that may qualify for Exempt Status:

**De-identified Data**: These are data sets that have had all of the identifying information removed and there is no way that the data can be linked to specific individuals. This means the data cannot contain any previous coding mechanisms, any characteristics of data which could make individuals’ identity known through a combination of data such as age, gender, and job title, or be identifiable through video or photographs.

**Coded Data**: If data sets are coded and there is an agreement in place where the key may not be released, this use does constitute human subjects research. For instance, school districts often use data share agreements with researchers to provide certain data for analysis. A copy of these agreements must be provided to IRB for review.

**Public Data**: These are data sets prepared with the intent of making them available to the public and have no individually identifiable private information. Individually identifiable data is anything that an individual can reasonably expect will not be made publicly available. For instance, SMU department faculty website information or census data.

If the use of secondary data is not ruled exempt status by the IRB, the IRB must review the research protocol before the data may be used. In such cases, the research will be considered as having expedited or full-board review status depending on the parameters of the research. As with any human subjects data, appropriate consent must be obtained. If it is not possible to obtain consent for the previously collected data, a waiver of
consent for the secondary data usage may be sought. The research cannot be completed if a waiver of consent is not granted.

**SMU Classroom Research**

Faculty of SMU classroom research are responsible for obtaining IRB approval, overseeing the projects, and ensuring the ethicality of the research. In addition, the faculty member must have completed CITI training.

SMU Classroom Projects/Training/Curriculum – includes any human subjects research conducted as part of a class. An example of this would be a research methods class. It is important to note that federal guidelines are clear that it is the IRB that makes the determination of whether IRB approval is needed for the research or whether it is Exempt. The faculty member must complete the Exempt status determination form and submit it to the IRB for review. In order to qualify as class-based research, the data must only be used for the purpose of teaching the class; the results will be only presented in the class. In addition, all of the following requirements must be met to be considered as class-based research. Again, the IRB will make the final determination when considering the following points:

- The project involves minimal risk.
- The project does not include any vulnerable populations.
- Participants are not pressured or coerced into participating.
- The data collected in such a manner that the subjects are not identifiable (e.g., names, emails, any audio/videotaping or pictures, etc. makes the data identifiable)
- Ask about sensitive topics (e.g., substance abuse, mental health issues or well-being, traumatic experiences, sexual abuse or orientation).
- The results of the project can only be presented to the SMU class or faculty for educational purposes; no publishing in any form of the data. No outside support or funding was used from an external organization in collecting, analyzing, or reporting results of this project.

**Student Research Projects (e.g., Independent Studies/Honors Theses/Dissertations)**

Student research projects involving projects that use systematic data collection with human subjects with the intent to contributing to general knowledge, fall under the normal IRB guidelines. It is important to note that these studies do NOT necessarily have to be published to be considered research.
Private Information/Behavior vs Public Information/Behavior

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 (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects (45 CFR 46.102(f)). Please contact the IRB office to ascertain whether data is considered public or private information in research.

Research Conducted Internationally

Research conducted outside the United States must still comply with SMU’s IRB policies and go through the IRB approval process. In addition, the research must comply with the host country’s standards for research involving human subjects. It is the responsibility of the Primary Investigator (PI) to be apprised of the host country’s standards for human subjects research. Further, the IRB understands that local customs and cultures may impact the research protocols; however, researchers are responsible for providing the IRB with the appropriate information needed for special considerations. Please complete the International Research Supplemental Form and include in your application submission.

Non-Compliance

Non-compliance occurs when human subjects research is conducted in a manner that disregards or violates Federal, state, and local regulations or SMUs policies regarding human subjects research. This includes any unapproved or non-compliant research activity where research subjects are placed at risk. SMU takes has a strong stance on non-compliance as it puts human subjects at risk as well as the University as a whole.

Once the IRB becomes aware of potential or allegations of research misconduct, they are required to investigate the matter. Whether research is suspended during the investigation will be determined by the seriousness of the allegations as well as the cooperation of the PI. Once the investigation is complete, one of three outcomes will be determined:

- No non-compliance found.
• Non-compliance issues found.
• Serious Non-compliance issues found.

Depending on the severity of the issues, the IRB may take the following possible actions.

**Possible IRB Actions**

If it is determined that the non-compliance is neither serious nor continuing, a corrective plan will be put in place to correct the compliance issues along with a timeframe for the corrections to be completed. The PI may also be required to create an action plan and submit it to the IRB. In addition, the IRB may require additional monitoring of the research.

If it is determined that the non-compliance is serious or continuing non-compliance the IRB will consider:

- Disallowance of data
- Suspension of the research
- Termination of the research
- Request oversight for the study by another researcher
- Additional monitoring activities
- Possible notification of OHRP and funding agency

**Examples of Compliance Issues**

- Conducting human subjects research without IRB approval or before official approval has been received by the PI in the form of a letter.
- Repeated or deliberate failure to obtain informed consent from participants in the approved manner. This also includes, but is not limited to, not consenting participants, not documenting the consent procedure, missing signatures, using unapproved or out-dated consents (consents should have an in-date IRB approval stamp).
- Modifying or deviating from the protocol without IRB permission. This includes, but is not limited to: survey items, questions, recruitment material, consent forms and process, experimental conditions, etc.
- Enrolling subjects who do not meet inclusion criteria
- Failure to maintain adequate records
- Failing to report or delaying reporting of unanticipated issues
- Repeated or deliberate omission of risk from the consent process
Repeated or deliberate omission of providing informed consent in the primary language of the participant

Failing to train and get research staff approved to work on the study

Not filing for continued review before approval expires

**Serious Non-Compliance Issues**

- Bringing harm to participants
- Exposing a participant to possible harm
- Compromising the privacy and confidentiality of participants
- Engaging in willful non-compliance
- Conducting research that is not ethical according to the IRB ethical principles

**Appeals**

*Denied Research*: If the IRB feels the risks of study participation outweigh the benefits of the research and the researcher disagrees with the IRBs decision, the researcher may initiate an appeal requesting reconsideration. The appeal must be submitted in writing to the IRB chair within 2 weeks of the decision. This appeal should include the researcher’s arguments for approval and any additional new information that would supportive information. If the IRB chair believes the new information warrants an appeal, the full IRB committee will hear the appeal at the next full-board meeting. The IRB’s determination of the appeal is final. However, if the appeal is denied, the researcher may submit a revised protocol for consideration.

*Denied Use of Data*: In the event a researcher has been found out of compliance in their research or does not have an approved protocol for research, the IRB may rule that specific data may not be published in affiliation of SMU. If the researcher disagrees with the IRBs decision, the researcher may initiate an appeal requesting reconsideration. The appeal must be submitted in writing to the IRB chair within 30 days of the decision. This appeal should include the researcher’s arguments for approval and any additional supportive information. If the IRB chair believes the new information warrants an appeal, the full IRB committee will hear the appeal at the next full board meeting. The IRB’s determination following the appeal is final.

*Authority of Appeal Process*: In the case of a decision to disapprove, suspend, terminate a project, or disallow usage of data, the decision may
NOT be reversed by any administrator at SMU. The IRB retains the final authority for approval of proposed research with human subjects.

**Reporting to Regulatory Agencies and Institutional Officials**

If the IRB determines that an adverse event, unanticipated problem, or non-compliance has occurred with a research study or if research is suspended or terminated, the IRB must report these incidences to appropriate authorities.

**Role of Other SMU Offices and the IRB (Contracts, Risk Management, Legal, Contract Management)**

The relationship between the IRB and other offices on campus can overlap in responsibilities. To alleviate confusion for the researchers, the IRB has a process in place for the Office of Risk Management, Office of Legal Affairs, and Grant and Contract Accounting. Once an IRB application is received and a determination is made that one of these three offices should be involved, a form will be completed and sent to the appropriate office via email with the PI copied. It is important to note that IRB approval is NOT contingent on approval from these other offices.

- The main role of the Office of Risk Management is to maintain strong partnerships with community members on all SMU campuses, to preserve life, protect property, reduce risk, and promote the educational objectives of SMU.

- The Office of Legal Affairs is responsible for provision of all legal services to the Board of Trustees, SMU’s officers, and authorized representatives of institutional interests for legal matters involving SMU.

- The role of the Grant and Contract Accounting is to manage the financial component of the University’s sponsored projects (externally funded, research, public service, training, and financial aid grants and contracts.)

**Researchers from Multiple Universities**

If the research study is being conducted onsite at multiple universities, SMU’s IRB must ensure that IRB approval has been obtained at each participating university before research commences at the site. If all of the data is collected at SMU, then the IRB does not have to have IRB approval from the other universities. Please contact the Director of Research Compliance to discuss your particular situation.
IRB Approval at Former University

If you have approval to conduct a study your former University, you may be required to transfer the study to SMU’s IRB. Please contact the Director of Research Compliance to discuss your particular situation.

Leaving SMU

If you are planning to leave SMU, before you leave you must complete one of the following:

- Transfer the IRB oversight of the research protocol to your new University
- Amend the study to replace the PI with an SMU appropriate PI
- Close your IRB protocol at SMU.

Effects of HIPPA (Health Insurance Portability and Accountability Act) on Research

Under HIPPA, participants have certain rights relating to their private health information (PHI). While SMU is not a fully covered entity under HIPPA, SMU research must be compliant with the rules on HIPPA.

Mandatory Reporting of Child and Elder Abuse

If there is a possibility that child or elder abuse may be discovered during the research process, a procedure outlining the reporting process must be included in the protocol before a study will be approved by the IRB.

Texas law requires anyone with knowledge of suspected child abuse or neglect to report it to the appropriate authorities. This report may be made to 1) any local or state law enforcement agency; or 2) the Department of Family and Protective Services. Please refer to SMUs Policy on this issue. In addition, Texas law also requires anyone with knowledge of suspected elder abuse or neglect to report it to the appropriate authorities. This report may be made to 1) any local or state law enforcement agency; or 2) Adult Protective Services.