Institutional Review Board
Research Handbook

Research Compliance
Office of Research and Graduate Studies
Southern Methodist University
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Purpose of this 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.

Resources

Important Contacts

Director of Research Compliance
Heather McClary, MPH
hpowell@smu.edu
214-768-2030

Compliance Coordinator
Laura Hamilton
lahamilton@smu.edu
214-768-4204

IRB Chair
Austin Baldwin, PhD
baldwin@smu.edu
214-768-1027

General Inquiries
researchcompliance@smu.edu
214-768-2033

Assistant Vice President for Research Integrity and Operations
Shannon Lunt, MS
slunt@smu.edu
214-768-2029

Training

CITI Training: https://www.citiprogram.org/ (access via SMU-networked computer)

NIH Training: https://phrp.nihtraining.com/

For registration instructions, visit the SMU Research Compliance website.

Code of Federal Regulations Title 45 Part 46 (45 CFR 46)
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

SMU Research Compliance Website
https://www.smu.edu/Research/ResearchServices/ResearchCompliance
Role, Authority, and Origins 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 of 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.

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.

Federally Mandated for Human Subjects Research

The Department of Health and Human Services (DDHS) established federal regulations (Title 45, Part 46 of the Code of Federal Regulations, also known 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.

Composition of the IRB

IRB Members

Federal regulations require that the SMU 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 Assistant Vice President for Research Integrity will appoint members to the IRB after consulting with the Director of Research Compliance and the IRB Chair. The IRB members will serve a two-year, renewable term.

IRB Chair

The chair of the IRB is appointed by the Assistant Vice President for Research Integrity and Operations. The chair will be appointed from the tenured faculty at SMU. The chair will serve a two-year renewable term.

IRB Administration

The Director of Research Compliance and the Compliance Coordinator serve as ex officio (i.e. non-voting) members at full board meetings.

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 (see SMU’s policy on conflict of interest). Consultants will serve only in an advisory role and will not be allowed to vote.
Definitions

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)).

Research

Federal Regulations define research as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102(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.”

Generalizable 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, and other non-peer reviewed formats with the intent of sharing.

Human Subjects

“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

Containing 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.

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))
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.

Privacy
An individual’s control over the extent, timing, and circumstances of sharing him/herself (physically, behaviorally, or intellectually) with others.

Confidentiality
The treatment of information disclosed in a trust relationship and with the expectation that it will not be divulged without permission to others in ways inconsistent with the understanding of the original disclosure.

Anonymous
No identifiers are collected that link information/records/samples to the individual from which they were obtained. Data collected in person cannot be described as anonymous, and the existence of a list of codes and associated identifiers means that data are not anonymous.

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)).

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 (1.16 and procedures7.7) for more information.

Principal Investigator (PI)
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.

Co-Principal Investigator (Co-PI)
Individual who assumes the same responsibilities as the Principal Investigator of a project, but who is not qualified under SMU policy to be a PI. This can include undergraduate and graduate students, as well as researchers not affiliated with SMU.
Undergraduate Program Director: A Principal Investigator may choose to include an Undergraduate Program Director as a Co-PI so they may be included in the official IRB correspondence related to the project. There are no additional project-related responsibilities assumed with this inclusion.

Key Personnel
An individual who interacts and/or intervenes with human subjects, handles personally identifiable data of human subjects, and/or contributes to the scientific development or execution of the project in a substantive way.

Adverse Event
All types of harm (including physical, emotional, social, economic, legal, and confidentiality) experienced by research participants, which do not necessarily have a causal relationship with participation in the research.

Unanticipated Problem
Any incident, experience, 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; and
- Suggests that the research places subjects or others at greater risk of harm than was previously known or recognized.

Who May Be a PI at SMU
- Any tenured and tenure-track SMU faculty and SMU librarians who have completed required human subjects research training.
- All SMU personnel who have a Research title and function at SMU who have completed required human subjects research training.
- Any instructor, visiting professor, clinical professor, professor of the practice who has approval from the Department Chair or Dean and have completed required human subjects research 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 required human subjects research 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 has completed required human subjects research training.

Who May NOT Be a PI at SMU
- Anyone who has not completed required human subjects research training.
- Undergraduate students
- Master’s level graduate students
- Anyone not a part of the SMU community

Personnel Responsibilities
Principal Investigator (PI)

- 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 required human subjects research 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 have the potential to harm participants of the research.
• Seeking a Continuing Review if the research goes beyond the initial one year approval. Continuing reviews should be submitted during active participant enrollment and analysis of identified data. It is the responsibility of the PI to notify the IRB when research is completed.

Co-Principal Investigators and Key Personnel

• 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 required human subjects research training
• 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

IRB Application 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 do this, researchers will complete an application found on the SMU IRB website and provide all supporting documents to researchcompliance@smu.edu.

Review Process

The Compliance Staff will review the application for completeness and request any needed information from the researchers. When complete, the Compliance Staff 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 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: Expedited review takes place throughout the calendar year. At least one member of the IRB will review the application 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. 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 deadlines for submission of applications is available on the Research Compliance website. All members of the IRB will receive a copy of the study to review. The researcher may be invited to attend the monthly IRB meeting to present their research and
answer clarification questions from the IRB. After the meeting, the researcher will be sent a letter requesting any needed modifications. Once the requested modifications have been addressed, the researcher will re-submit the application materials to the Research Compliance Staff. 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.

Protocol Materials the IRB Must Review

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

Types of Review

Exempt Review

It is the responsibility of the IRB to make fair and consistent decision as to what studies will be qualify for exemption 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, the research must involve no more than minimal risk. Next, the research must fit into one of the following six categories.

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 directly identified, 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 2 (above), 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, but that is not eligible for an exemption. 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, heel stick, ear stick, or venipuncture as follows:
   • From healthy, non-pregnant 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 non-disfiguring 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, electroretinography, 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 non-research 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 exempt or expedited 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.

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 four to six weeks 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.
Lapse in Approval Review

A lapse in IRB approval of research occurs whenever an investigator has failed to provide continuing review information to the IRB or the IRB has not conducted a continuing review and re-approved the research – with or without conditions – by the expiration date of the IRB approval. In this case, a Lapse in Approval Form must be submitted. The IRB will determine if the OHRP or applicable funding agencies should be notified, and if the data usage is available. The research may continue only after the PI receives written approval from the IRB.

Chair-Endorsed Administrative Review

Specific amendments and Continuing Review may be reviewed by the Compliance Staff for approval. These reviews would be allowed for the following:

- Addition / Deletion of Personnel
- Change in Project Title or Funding Source
- Continuing Review when no participants have been enrolled, or if the study is continuing with no participant involvement

Criteria Used to Evaluate IRB Proposals

- Have the risks to participants been mitigated or minimized?
- Are the anticipated and potential risks reasonably balanced with the anticipated benefits of the research?
- Are the recruiting and selection processes of subjects fair/equitable (i.e., 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?

Types of Risk

Examining risk is one of the main foci of the IRB when reviewing an 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 participant’s 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): pregnant women, prisoners, and children. However, the guidelines suggest in addition to these defined categories, people with impaired cognitive ability, or economically and educationally disadvantaged people, may be considered as vulnerable populations.

Individuals with impaired capacity to consent 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 any other reduction of 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 will 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.

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. Expedited and Full board studies must demonstrate a consent process; however, Exempt studies may be limited to a verbal consent.

- 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 participants 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 information
- 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.

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. When a waiver is granted, a verbal consent is required.

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 require informed consent.

**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.

**Approved Pending Modifications/Training Completion**

Minor changes to the protocol or training completions are needed before research may begin. The IRB will enumerate the requested changes and/or required training(s), and the applicant must re-submit the modified protocol for confirmation.

**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.

**Changes to the Protocol (Amending your study)**

**Expedited/Full Board Studies**

Any proposed changes to the study must be approved by the IRB. This includes, but is not limited to, 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.

**Exempt Studies**

Most modifications to exempt research may be done at the discretion of the principal investigator without prior IRB approval. Some changes do require pre-approval, however.

**Types of Changes Requiring IRB Review**

- Addition of research personnel
- Change in principal investigator
- Any change that increases the risk to the participant
- Addition of children or prisoner participants
- Changes in survey or interview questions (addition or deletion of questions or wording) that change the level of risk or adds questions related to sexual activity, abuse, past or present illicit drug use, illegal activities, questions reasonably expected to provoke psychological anxiety, or would make participants vulnerable, or subject them to financial, psychological or medical risk
• Changes that impact the category of exemption or add additional exemption categories
• Changes that add procedures or activities not covered by the exempt category under which the study was originally determined to be exempt
• Changes requiring additional participant identifiers that could impact the exempt category or determination
• Addition of a new recruitment strategy
• Increase in the planned compensation to participants

Types of Changes NOT Requiring IRB Review
• Removal of procedures
• Document changes that do not modify the intent of the content (e.g., typographical error corrections, improvements for clarity)
• Modification to number of participants

Please contact Research Compliance for guidance regarding amendments to exempt studies.

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 to provide an update since the last continuing review and indicate that all research activity has ended.

Reporting Adverse Events and Unanticipated Problems
Federal regulations (CFR46.103(b)(5)) require the IRB to ensure that investigators promptly report “any unanticipated problems involving risk to subjects or others.” The reporting requirement applies to all unanticipated problems, including unanticipated adverse events (see definition of unanticipated problem and adverse event). If there are unanticipated problems involving risk to participants, researchers must notify the IRB Chair and the Director of Research Compliance within 24 hours of the incident at researchcompliance@smu.edu.

An Unanticipated Event 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 corrective actions are implemented quickly to protect other participants from preventable harm. These regulations also require critical incidents or unanticipated events to be reported to federal agencies (e.g. OHRP, NSF, NIH) by the IRB.

Additionally, other types of events should be reported to the IRB. Examples include:

• Unanticipated changes to a 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
• Re-consenting of participants
• Additional monitoring requirements
• Suspension of enrollment of new participants
Suspension of the research study
Training of the research team

Non-Compliance

Non-compliance occurs when human subjects research is conducted in a manner that disregards or violates Federal, state, and local regulations or SMU 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.

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 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

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

Examples of Compliance Issues

- Conduct of 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 outdated consents (consents should have an in-date IRB approval stamp).
- Modification or deviation 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.
- Enrollment of subjects who do not meet inclusion criteria
- Failure to maintain adequate records
- Failure to report or delay in reporting of unanticipated problems
- Repeated or deliberate omission of risk from the consent process
- Repeated or deliberate failure to provide informed consent in the primary language of the participant
- Failure to train and get research staff approved to work on the study
- Failure to submit study for continuing review before approval expiration date (Lapse in approval)
Examples of 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 of IRB Decisions

Denied Research

If the IRB feels the risks of study participation outweigh the benefits of the research and the researcher disagrees with the IRB’s 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 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 with SMU. If the researcher disagrees with the IRB’s 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.

Human Subjects Research Training

All research personnel, including personnel outside of SMU, who are listed on an IRB protocol as a PI, Co-PI, or key personnel must complete required human subjects research training. The training dates and/or completion certificates of all personnel 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 and NIH training is good for 3 years and then must be renewed.

Two human subjects research training options are available:

CITI

Research personnel affiliated with SMU may complete the Collaborative Institutional Training Initiative (CITI) training. Instructions for registration may be found on the Research Compliance website. Personnel may select one of three human subjects research training courses: Biomedical Research, Social & Behavioral Research, or IRB-Determined Exempt status.
Research personnel NOT affiliated with SMU and/or those who prefer to take the course in Spanish may complete the NIH-sponsored training. Instructions for registration may be found on the Research Compliance website. The NIH training completion certificate must be provided to the IRB.

**Secondary Data**

Secondary use of data applies to activities that involve secondary analysis or use of 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.

Secondary use of data may not fit the definition of human subjects research, or it may qualify for an exemption (see exemption category 4). As with any other human subjects research, the determination as to whether secondary data use is considered human subjects research and/or exempt must be made by the IRB, and not by researchers. Below are some examples of secondary data that may not be human subjects research and/or qualify for an exemption:

*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, or any characteristics which could make individuals’ identities 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. For instance, SMU department faculty website information or census data.

If the IRB determines that the use of secondary data is human subjects research and does not qualify for an exemption, 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.

**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.

**SMU Classroom Research**

This includes any research involving human subjects conducted as part of a class. Most types of classroom research would not fit the definition of human subjects research, according to 45 CFR 46. However, it is important to note that federal guidelines are clear that the IRB makes this determination, not the faculty member. The faculty member can complete the Exempt status determination form and submit it to the IRB for review, or an informal review of the proposed classroom research can be performed via communication (e-mail or phone) directly with Research Compliance and the IRB. In order to qualify as classroom research, the data must only be used for the purpose of teaching the class and the results can be
only presented in the class. In addition, all of the following requirements must be met to be considered classroom 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 (names, emails, any audio/ videotaping or pictures, etc. make the data identifiable).
- The project does not ask about sensitive topics (e.g., substance abuse, mental health issues or well-being, traumatic experiences, sexual abuse or orientation).
- No support or funding from an external organization was used for collecting, analyzing, or reporting of the project.

**Student Research Projects**

Student research projects that use systematic data collection with human subjects with the intent to contributing to general knowledge (intent to publish) fall under the normal IRB guidelines, and are therefore subject to the IRB approval process. It is important to note that these studies do NOT necessarily have to be published to be considered research. In addition, student research projects require sponsorship by a qualified principal investigator.

**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 Principal Investigator (PI) to be familiar with 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.

**Research at Multiple Universities**

Some SMU researchers may choose to conduct studies onsite at multiple universities. In these cases, the SMU IRB may be considered the “IRB of Record.” The SMU IRB must ensure that IRB approval has been obtained at each participating university before research commences at the site. This can involve the external university IRB relying on the SMU IRB’s approval of the protocol, or it can involve full IRB approval at the external university. In general, the SMU-approved protocol must be submitted to the external university IRB, and a collaborator/sponsor at the external university must be established. Approval by the SMU IRB can sometimes be expedited by limiting the number of external university study sites listed in the original application, and adding additional external university study sites via amendments. Please contact Research Compliance to discuss your particular situation.

**Reliance**

Occasionally, researchers and institutions not affiliated with SMU may choose to use SMU as a study and/or recruitment site. In these cases, the SMU IRB can rely on another IRB’s review and approval of the protocol. This is called “Reliance.” In order to do this, the SMU IRB needs to be provided with all approved study materials, including the application form, recruitment scripts, informed consents, data collection instruments, and approval letters. Upon receipt of these materials, the SMU IRB will conduct a risk assessment. If the SMU IRB agrees to rely on the outside IRB’s approval of the protocol, the outside researcher or institution will be notified. Recruitment and/or data collection at SMU may NOT begin until the SMU IRB has had the opportunity to review the study materials and grant approval.
Transfer of IRB Approval
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 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.

Roles of Other SMU Offices
The relationship between the IRB and other offices on campus can overlap in responsibilities. To alleviate confusion for the researchers, the IRB has processes 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).

ClinicalTrials.gov
Some clinical trials must be registered on the ClinicalTrials.gov website. In order to be considered an Applicable Clinical Trial, thus requiring registration, all of the following criteria must be met:

- The study must be interventional (i.e., participants are assigned prospectively to an intervention or interventions according to a protocol to evaluate the effect of the intervention(s) on biomedical or other health-related outcomes)
- At least one study facility must be located in the United States or a U.S. territory OR the study must be conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE)
- The study must evaluate at least one drug, biological, or device product regulated by the U.S. FDA
- The study must be other than a Phase 1 trial of a drug and/or biological or device feasibility study

The Responsible Party (usually the principal investigator) is required to keep the ClinicalTrials.gov registration current and free of errors. If an investigator chooses to voluntarily register his or her human subjects research study on ClinicalTrials.gov, s/he is also required to keep the registration current and free of errors.

HIPAA
Under HIPAA, participants have certain rights relating to their protected health information (PHI). While SMU is not a fully covered entity under HIPAA, SMU research must be compliant with the rules of HIPAA.
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 SMU’s 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.

Decision Charts

The graphic aid charts on the following pages act as a guide for IRBs, investigators, and others to decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR 46.

http://www.hhs.gov/ohrp/regulations-and-policy/decision-trees/

- Chart 1: Is an Activity Research Involving Human Subjects?
- Chart 2: Is the Human Subjects Research Eligible for Exemption?
- Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?
- Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?
- Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimens) Apply?
- Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?
- Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?
- Chart 8: May the IRB Review Be Done by Expedited Procedures?
- Chart 9: May the IRB Continuing Review Be Done by Expedited Procedures?
- Chart 10: May Informed Consent Be Waived or Consent Elements Be Altered under 45 CFR 46.116(d)?
- Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?
Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

Start here: Is it research?

Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? [45 CFR 46.102(d)]

Activity is research. Does the research involve human subjects?

Does the research involve obtaining information about living individuals? [45 CFR 46.102(f)]

The research is not research involving human subjects, and 45 CFR part 46 does not apply.

Does the research involve intervention or interaction with the individuals? [45 CFR 46.102(f)(1), (2)]

Activity is research involving human subjects. Is it covered by the regulations?

Is it conducted or supported by HHS? [45 CFR 46.101(a)(1)]

The research involving human subjects is covered by the regulations.

Does the institution hold an FWA under which it applies 45 CFR 46 to all of its human subjects research regardless of the source of support?

Unless exempt under 45 CFR 46.101(b), 45 CFR part 46, subpart A applies to the research, and as appropriate subparts B, C, and D also apply.

The research involving human subjects is NOT covered by the regulations.

Go to Chart 2

Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]
Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

Has HHS prohibited exemption of the human subjects research? (All research involving prisoners, some research involving children.) [Footnote 1 to 45 CFR 46.101(b), 45 CFR 46.401(b)]

- NO
  - Will the only** involvement of human subjects be in one or more of the following categories?
    - YES: Research conducted in established or commonly accepted educational settings, involving normal education practices?
      - NO: If not exempt under (b)(1)
        - YES: Research involving the use of educational tests, survey procedures, interview procedures, or observation of public behavior?
          - NO: If not exempt under (b)(2) or (b)(3)
            - YES: Research involving collection or study of existing data, documents, records, or pathological or diagnostic specimens?
              - NO: If not exempt under (b)(4)
                - YES: Research studying, evaluating, or examining public benefit or service programs?
                  - NO: If not exempt under (b)(5)
                    - YES: Research involving taste and food quality evaluation or consumer acceptance studies?
                      - NO: If not exempt under (b)(6)

- YES: No exemptions to 45 CFR part 46 apply. Provisions of 45 CFR subpart A apply, and subparts B, C, and D also apply if subjects are from covered vulnerable populations.

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.
Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

From Chart 2

Is the research only** conducted in established or commonly accepted educational settings? (Including but not limited to schools and colleges. May include other sites where educational activities regularly occur.)

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

NO

Research is not eligible for 45 CFR 46.101(b)(1) exemption.

Next

YES

Does the research study involve only normal education practices? (Such as research on regular and special education instructional strategies, or research on effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.)

NO

Return to Chart 2 and consider whether 45 CFR 46.101(b)(2) exemption applies.

YES

Research is eligible for 45 CFR 46.101(b)(1) exemption from 45 CFR part 46 requirements.

February 16, 20126
Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

February 16, 2016

From Chart 2

Does the research involve only** the use of educational tests, survey procedures, interview procedures, or observation of public behavior?

YES

No research involving only** educational tests or observation of public behavior without participation by the investigator in the activities being observed is exempt under 45 CFR 46.101(b)(2).

NO

Does the research involve children to whom 45 CFR part 46, subpart D applies?

YES

Research is not eligible for exemption under 45 CFR 46.101(b)(2).

NO

Is the information obtained recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, and could any disclosure of the human subjects' responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?

YES

Research is eligible for exemption under 45 CFR 46.101(b)(3) from 45 CFR part 46 requirements.

NO

Research is not eligible for exemption under 45 CFR 46.101(b)(2) or (b)(3).

Return to Chart 2 and consider whether 45 CFR 46.101(b)(4) exemption applies.

** "Only" means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

Are the human subjects elected or appointed public officials or candidates for public office? (Applies to senior officials, such as mayor or school superintendent, rather than a police officer or teacher.)

YES

Research is eligible for exemption under 45 CFR 46.101(b)(3) from 45 CFR part 46 requirements.

NO

Does any Federal statute require without exception that the confidentiality of personally identifiable information will be maintained throughout the research and thereafter?

YES

Research is eligible for exemption under 45 CFR 46.101(b)(3) from 45 CFR part 46 requirements.

NO

However, the 45 CFR 46.101(b)(3) exemption might apply.
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?

From Chart 2

Does the research involve only** the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens? *

(“Existing” means existing before the research is proposed to an institutional official or the IRB to determine whether the research is exempt.)

YES

Are these sources publicly available?

YES

Research is eligible for exemption under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.

NO

NO

Will information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects?

YES

Research is not eligible for exemption under 45 CFR 46.101(b)(4) from 45 CFR part 46 requirements.

NO

Return to Chart 2 and consider whether 45 CFR 46.101(b)(5) exemption applies

** “Only” means that no non-exempt activities are involved. Research that includes exempt and non-exempt activities is not exempt.

* Note: See OHRP guidance on research use of stored data or tissues and on stem cells at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-research-involving-stem-cells/index.html and on coded data or specimens at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html for further information on those topics.

February 16, 2016
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?

From Chart 2

Is the research or demonstration project conducted or approved by the Department or Agency Head?

** "Only" means that no non-exempt activities are involved. Research that induces exempt and non-exempt activities is not exempt.

YES

Does the research or demonstration project involve only** the study, evaluation, or examination of:

Public benefit or service programs;

NO

Procedures for obtaining benefits or services under public benefit or service programs;

NO

Possible changes in or alternatives to public benefit or service programs or to procedures for obtaining benefits or services under public benefit or service programs;

NO

Possible changes in methods or levels of payment for benefits or services under those public benefit or service programs?

YES

Research is eligible for exemption under 45 CFR 46.101(b)(5) from 45 CFR part 46 requirements.*

NO

Research is not eligible for exemption under 45 CFR 46.101(b)(5).


February 16, 2010
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

From Chart 2

Does the research involve only** a taste and food quality evaluation or a food consumer acceptance study?

YES

Are wholesome foods without additives consumed?

YES

Research is eligible for exemption under 45 CFR 46.101(b)(6) from 45 CFR part 46 requirements.

Other Federal, State and local laws and/or regulations may apply to the activity. [45 CFR 46.101(f)]

NO

IS food consumed that contains a food ingredient, 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?

YES

NO

Research is not eligible for exemption under 45 CFR 46.101(b)(6).

Go to Chart 8

February 16, 2016
Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

From Chart 2, or 7

Has the research been previously reviewed and approved by the IRB?

YES

Is the review a continuing review? [45 CFR 46.100(d)]

NO

Does the research present no more than minimal risk to human subjects? and does the research involve only procedures included in categories 1 through 7 on the list of categories of research that may be reviewed through an expedited review procedure? [45 CFR 46.110(b)(1)]

YES

Go to Chart 9

NO

Does the review involve a minor change in approved research during the (one year or less) period of approval? [45 CFR 46.110(b)(2)]

YES

Review by convened IRB is required.

NO

Are measures in place to make risks no more than minimal?

YES

Go to Chart 10

NO

Could identification of subjects put them at risk of criminal or civil liability, or be socially or economically damaging? [Paragraph (C) of Categories.]

YES

Research is eligible for IRB review through expedited procedures. Agency head may restrict, suspend, terminate or choose not to authorize an institution's or IRB's use of the expedited review procedure. [45 CFR 46.110(d)]

NO

February 16, 2016

Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?


From Chart 8

Has the research been previously reviewed and approved by the IRB using expedited procedures?

- **YES**
  - Have conditions changed such that the research is no longer eligible for expedited review (e.g., protocol change, or experience shows research to be of greater than minimal risk)?
    - **YES**
      - Review by convened IRB is required.
    - **NO**
      - Go to Chart 10

- **NO**
  - Have conditions changed to make the research eligible for expedited review under the applicability criteria and categories 1 through 7 on the list of categories that may be reviewed by expedited procedures (e.g., research is within those categories and experience confirms research to be of no greater than minimal risk) [45 CFR 46.110(a)]
    - **YES**
      - Research is eligible for IRB review through expedited procedures.
    - **NO**
      - Go to Chart 10

**Category 8**

(a) For this site: Is the research permanently closed to enrollment of new subjects? and Have all subjects completed all research-related interventions? and Does the research at this site remain active only for long-term follow-up of subjects?

- **YES**
  - (c) Are the remaining research activities at this site limited to data analysis?
    - **YES**
      - Is the research conducted under an IND or IDE?
    - **NO**
      - Go to Chart 10

(b) Have no subjects been enrolled at this site? and Have no additional risks been identified anywhere?

- **YES**
  - Has the IRB determined and documented at a convened meeting that the research involves no greater than minimal risk?
    - **YES**
      - Go to Chart 10
    - **NO**
      - Go to Chart 10

February 16, 2016
Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?

*(Note: If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. [See 45 CFR 46.408(c)])*

From Chart 8 or 9

Will the research or demonstration project be **conducted by or subject to the approval of state or local government officials?**

45 CFR 46.116(c)(1)

*YES*

Is the project designed to study, evaluate, or otherwise examine: (i) Public benefit of 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? 45 CFR 46.116(c)(1)

*NO*

Will the research involve greater than minimal risk, as defined in Section 46.102(i)?

45 CFR 46.116(d)(1)

*NO*

Is it practicable to conduct the research **without** the waiver or alteration? 45 CFR 46.116(d)(3)

*YES*

No waiver of informed consent or alteration of consent elements is allowed. 45 CFR 46.116(c)(2)

*NO*

Will waiving or altering the informed consent adversely affect the subjects' rights and welfare? 45 CFR 46.116(d)(2)

*YES*

If informed consent is not waived entirely

Will pertinent information be **provided to subjects later**, if appropriate? 45 CFR 46.116(d)(4)

*NO*

Go to Chart 11

*YES*

Waiver of informed consent or alteration of consent elements is allowed if IRB documents these findings and approves waiver or alteration.

*Note: See OHRP guidance on informed consent requirements in emergency research at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html for further information on emergency research informed consent waiver.*

February 16, 2016
Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

From Chart 10

Would the consent document be the only record linking the subject and the research and would the principal risk be potential harm resulting from a breach of confidentiality? [45 CFR 46.117(c)(1)]

NO

Does the research present no more than minimal risk and involve no procedures for which written consent is normally required outside the research context? [45 CFR 46.117(c)(2)]

YES

IRB may waive the requirement for a signed consent form for some or all subjects.

AND

If IRB Allows Waiver of Documentation Under 45 CFR 46.117(c)(1)

Investigator will ask each subject if he or she wants documentation linking the subject with the research. [45 CFR 46.117(c)(1)]

Subject's wishes will govern whether informed consent is documented. [45 CFR 46.117(c)(1)]

END

February 16, 2016