



Tarrant County College District

Institutional Review Board (IRB) Charter

2026

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*With appreciation to Sinclair Community College for permission to adapt its IRB model to suit TCCD.



Institutional Review Board Charter

I. Introduction

The Tarrant County College District (TCCD) encourages and supports the scholarly endeavors of all students and TCCD faculty and staff. Pursuit of scholarly work and research often involves the use of human subjects for data collection and analysis. TCCD defines research as the *systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalized knowledge*. TCCD's Institutional Review Board (IRB) reviews human subjects research proposals to ensure that: (a) the rights and welfare of human subjects used in research studies are protected, (b) risks have been considered and minimized, (c) the potential for benefit has been identified and maximized, (d) all human subjects volunteer to participate in research only after being provided legally effective informed consent and (e) any research is conducted in an ethical manner and in compliance with established standards. Those individuals seeking to conduct research using human subjects may not solicit subject participation or begin data collection until they have obtained clearance by the TCCD IRB.

Some research projects involving human subjects are exempt from IRB approval requirements. The types of research generally exempt from IRB approval requirements include normal educational practices, such as: (a) work undertaken as a part of a course, (b) educational tests when the subjects are not identified and (c) surveys or interviews in which the subjects volunteer and are not personally identified.

The IRB for human subjects research at TCCD has responsibility to oversee procedures for carrying out the TCCD's commitment to protect human subjects in research. The TCCD IRB will: (a) review, (b) approve, (c) disapprove or (d) require modifications to submitted research proposals that involve human subjects. The TCCD's IRB does not evaluate the merits of research design or review proposals for contribution to scholarly literature. The sole role of the TCCD IRB is to review research proposals for standards of compliance in regard to participant risk, informed consent, and confidentiality.

II. Institutional Authority

This Charter establishes and empowers the TCCD IRB for the protection of human subjects. Currently TCCD has one Committee registered with the federal [Office for Human Research Protections](#) (OHRP) as its Institutional Review Board (IRB 00009412). This committee is hereinafter referred to as the “IRB.” According to the terms of the [Federal-Wide Assurance](#) (FWA), TCCD adopts the following reporting procedure:

Principal Investigator(s) and TCCD employees are required to report to the Chair of the IRB Committee any of the following upon knowledge of the following:

- unanticipated problems involving risks to subjects or others **and**
- serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

Upon receipt of such information, or if a research project is suspended or terminated by the IRB, the IRB Chair will make a written report to the TCCD IRB, TCCD Chancellor, head of any department or agency conducting or supporting said research, any applicable regulatory body and the OHRP.

III. Purpose

The primary purpose of the IRB is to protect the welfare of human subjects used in research.

IV. Basic Principles

- A. The basic principles that govern the IRB in assuring that the rights and welfare of subjects are protected are contained in Ethical Principles and Guidelines for the Protection of Human Subjects of Research ([The Belmont Report](#)) and The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979.
- B. The following principles apply to all research, including student projects involving human subjects at TCCD to ensure that adequate safeguards are provided:
 - Subjects’ legal rights will be respected; their rights to privacy, dignity and comfort will be considered in approving proposed research.
 - Risks to subjects must be reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.
 - Adequate provision(s) must be made for all facilities, procedures, and professional attention necessary for the protection of the individual as a research subject.
 - Adequate provisions should be made for recruiting a subject population that is representative of the population base in terms of gender and minority representation, unless scientifically justified.
 - Research involving human subjects must be supervised by qualified persons, including qualified clinicians for all study-related healthcare decisions.
 - Participation in a human subject in research must be voluntary, and the right to withdraw at any time must be provided. Information provided to gain subject consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.
 - All research programs that involve human subjects must be reviewed by and receive approval by the TCCD IRB **prior** to their initiation or **prior** to initiating any changes to the proposal.
 - Continuing research programs are subject to periodic review, to be carried out at least once a year.
- C. In making the decision to conduct an IRB review of submitted proposals, the IRB’s first priority is to focus on factors promoting TCCD’s mission. Any submitted proposal must meet the minimum standard of having the likelihood of providing knowledge that contributes to the long-term success of TCCD’s faculty, staff, and students. In reaching its conclusions concerning the granting of an IRB

review, the IRB will take into consideration the following factors:

- Has the researcher made a strong and compelling case that the research will provide insight into learning and student success factors, and is the research aligned with TCCD's mission?
- Has the proposal clearly articulated how findings will be communicated to the TCCD community?
- Have all costs which will be incurred by the TCCD community been fully considered? Do the benefits outweigh the costs and have provisions been made to reimburse TCCD for any unusual data collection expenses?
- Is the research in compliance with [Family Educational Rights and Privacy Act \(FERPA\)](#) requirements?
- In the opinion of the IRB, is the research design sufficiently rigorous to lead to meaningful insights?
- Has the researcher: identified a TCCD full-time faculty or staff member who is willing to serve as the internal sponsor for the research, obtained written acceptance of said sponsorship and identified the value of the research findings to his/her area of responsibility?
- In the opinion of the IRB, have the individuals making up the research sample been overly burdened with requests to serve as research subjects?

V. **The Authority of the IRB**

- A. TCCD holds a FWA through OHRP. As part of this Assurance, TCCD agrees to consider all research involving the use of humans as research participants as being subject to federal regulations, regardless of the source of funding, if one or more of the following apply:
- The research is sponsored by TCCD (unless the research is conducted at another institution with which TCCD has an IRB Authorization Agreement as specified in TCCD's FWA); or
 - The research is conducted by or under the direction of a TCCD employee or agent (unless the research is conducted at another institution with which TCCD has an IRB Authorization Agreement as specified in TCCD's FWA); or
 - The research is conducted by or under the direction of any TCCD employee or agent using any TCCD property or facility; or
 - The research involves the use of TCCD's non-public information to identify or contact human research subjects or prospective subjects.

In some instances, students may be involved in course activities such as questioning, participation in minimally physically stressing classroom exercises, observing and/or interacting with other individuals. The course instructor is responsible for determining whether such activity is classified as those kinds of activities that require IRB approval. If the instructor has any doubt concerning the classification of these activities, he/she is encouraged to complete a Research Proposal Form for approval and submit it along with the proposal and any accompanying consent form(s), cover letter(s) and/or questionnaire(s) in order to obtain the guidance of the IRB regarding these activities.

- B. The IRB reviews all projects and programs involving human subjects in accordance with this Charter and applicable federal regulations.
- C. The IRB has approval authority of human subject proposals and can disapprove, modify, or approve studies based upon consideration of any issue it deems relevant to human subject protection.
- D. The IRB has authority to require progress reports from investigators and oversee the conduct of the study.
- E. The IRB has authority to suspend or terminate approval of a study, or to place restrictions on a study, when this is deemed to be in the best interests of the subjects in that study.
- F. The IRB has authority to observe the informed consent process as practiced by any investigator

or authorized person in any approved proposal especially in cases where the consentor is from a vulnerable population (e.g., children (Under 18), pregnant women, fetuses, neonates, prisoners (Individuals involuntarily detained), individuals with impaired decision-making capacity or who are economically or educationally disadvantaged).

- G. The IRB has the authority to access, and to make copies of, records related to any research approved by the IRB (or another body under an IRB Authorization Agreement), regardless of the location of those records, for any reason. Where feasible, appropriate notice will be given regarding the need to review, copy or duplicate records while being sensitive to causing the least inconvenience or disruption of on-going research.

VI. The IRB's Functional Relationships

The IRB advises and makes recommendations to the Chancellor, policy and administrative bodies and any member of the TCCD community on all matters related to the use of human subjects in research.

VII. The Membership of the IRB

- A. The IRB is composed of at least five voting members. Alternates and non-voting members may also be appointed, with alternates authorized to vote at convened meetings only in the absence of the member for whom they are the designated alternate. Although an alternate may be designated for more than one IRB member, each alternate may represent only one regular member at a convened meeting. All appointments are made by Executive Memorandum and reported to OHRP.
- B. The IRB is composed of members with varying backgrounds and expertise in specific areas to provide complete and adequate review of the research. Committee members should possess not only broad specific competence sufficient to comprehend the nature of the research, but also other competencies necessary for judgments as to the acceptability of the research in terms of TCCD: (a) regulations, (b) relevant law, (c) ethical standards and (d) standards of professional practice. Consultants may be used to review proposals for which additional expertise is needed.
- C. IRBs must make every effort to ensure their membership is not composed entirely of men or entirely of women, at least one member whose primary concerns are in science areas, one whose primary concerns are in nonscientific areas, and at least one member who is not otherwise affiliated (either directly or through immediate family) with TCCD.
- D. No person shall be excluded from serving on the IRB based on: (a) race, (b) color, (c) religion, (d) sex, (e) age, (f) national origin, (g) veteran status or (h) disability.

VIII. MANAGEMENT OF THE IRB

- A. The IRB Chair has authority to sign all IRB action items.
- B. The IRB Vice Chair is a voting member of the IRB and presides over all convened IRB meetings in the absence of the Chair. The Vice Chair is appointed by the Chair and has authority to sign all IRB action items in the absence of the Chair.
- C. Members and alternates of the IRB are appointed by the IRB Chair for tenure of three (3) years. However, the term of appointment may be terminated with notice from the Committee member to the Chair or by notice from the Chair. If a member finds that he/she is unable to attend meetings for an extended period, as a consequence of unavoidable conflicting activities, the IRB Chair must be informed so that a replacement may be appointed. Additionally, members may be removed from the IRB before their term is completed for reasons of poor attendance for which there is not reasonable justification, or for other manifestations of unwillingness or incapability to serve the committee adequately. In either event, the Chair will appoint a replacement. Tenure on the IRB may be extended by mutual agreement between the member and the Chair.
- D. All IRB members are required to undergo formal training at the time of their initial appointment. Online trainings that satisfy this requirement are offered by the U.S. Department of Health and Human Services - [Office for Human Research Protections \(OHRP\)](#), [Collaborative Institutional Training Initiative \(CITI Program\)](#) and [The Association of Clinical Research Professionals \(ACRP\)](#). IRB member training certificates are maintained and stored in TEAMS. Human Research Protection

Training must be renewed every three years.

- E. Full-time and adjunct faculty serving as IRB members while off contract during the summer may receive a stipend from their administrative department, with compensation allowed for up to 10 hours per month.
- F. Educators Legal Liability insurance coverage for IRB members is provided through TCCD's insurance program while acting within the scope of their duties as members of the committee. Such protections are subject to the terms and conditions of the insurance policy.
- G. Consultants with competence in specific areas may be used when deemed appropriate.

IX. Conflict of Interest

A conflict of interest exists when an individual's private interests (such as financial gain, personal relationships, or professional affiliations) could potentially compromise or have the appearance of compromising their professional judgment or objectivity in conducting research.

Examples of financial conflicts of interest often include:

- Holding equity (stock or stock options) in a company that could benefit from the research outcomes.
- Receiving substantial income or compensation from a company involved in the research.

Having intellectual property rights (patents, copyrights) related to the research. The IRB plays a crucial role in reviewing and managing identified conflicts of interest to ensure the protection of human subjects.

This might involve:

- **Disclosure in Consent:** Requiring the conflict of interest to be disclosed to research participants in the Informed Consent form.
- **Independent Oversight:** Requesting independent monitoring of the research, particularly for high-risk studies.
- **Modifying Research Plans:** Requiring changes to the research plan to minimize bias.
- **Limiting Investigator Involvement:** Restricting the role of the conflicted investigator in certain aspects of the research, such as recruitment or data analysis.

Inquiring about possible conflicts of interest is a vital step in promoting transparency, upholding ethical standards, and safeguarding the rights and welfare of individuals participating in research studies.

- **Protecting Human Subjects:** Conflicts of interest can potentially bias various aspects of a research study, including the design, conduct, and reporting of results, potentially compromising the safety and welfare of participants.
- **Maintaining Research Integrity:** Transparency regarding potential conflicts helps ensure the scientific integrity of the research and the objectivity of the data.
- **Regulatory Compliance:** Federal regulations, particularly those concerning Public Health Service (PHS) funding, mandate institutions have policies for identifying and managing financial conflicts of interest in research.

A. IRB Members

An IRB member is said to have a conflicting interest whenever that IRB member, spouse, or dependent child of the member:

- Is the PI and/or Co-PI on the proposal.
- Has a significant financial interest in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could influence the value of the financial interest.
- Acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB.
- Has identified him or herself for any other reason as having a conflicting interest. It is the responsibility of each IRB member to identify and avoid any situations in which he or she, either personally or by virtue of their position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection

with a matter before an IRB of which they are a member. If assigned as a reviewer for a matter with which the IRB member feels that he or she may have a conflict of interest, the IRB member must notify the IRB Chair immediately so the matter may be reassigned to another reviewer.

- In order not to delay the review process, it is essential that potential reviewers peruse the matters for which they are assigned reviewers immediately upon receipt to determine whether they may have a conflict.
- Typically, there are three distinct phases of an IRB's consideration of a matter: discussion, deliberation, and actions (including vote). In general, IRB member(s) who have a real or perceived conflict of interest may remain in the meeting room, at the discretion of the IRB Chair during the discussion of the matter in order to provide answers to questions, clarifications, etc. However, said member must leave the meeting room for deliberations and actions/votes regarding the matter.

Minutes of IRB meetings will reflect the absence of a member (by name) when he or she leaves the meeting during deliberations and actions regarding matters for which they have, or may be perceived to have, a potential conflict of interest.

B. Principal Investigators

Federal regulations, state laws, and TCCD policies recognize that researchers may have monetary interests in research sponsors and/or in entities with business interests closely related to their research. When conducting research involving human subjects, researchers should submit financial disclosures prior to or concurrent with their application for IRB approval of a new project and at the time of continuing review.

For New Projects, disclosure is required if:

- The study is PHS-funded.
- The study is privately funded or supported.
- The study is FDA-regulated.
- Any Investigator has a significant financial interest when the research is unfunded and not FDA-regulated.

C. Conflict of Interest Policy & Procedure

- Investigators shall not be involved in the selection of IRB members.
- Investigators will be asked whether they have a personal stake in any commercial enterprise associated with any aspect of the proposal, and, if yes, to fully explain and identify the safeguards taken to prevent investigator bias in subject recruitment and/or the consent process. TCCD investigators must comply with TCCD's Board Policy Manual, Section DBD - Employment Requirements and Restrictions: Conflict of Interest Policy.
- Investigators and IRB members who are TCCD employees, and who apply for federal or state government grants and contracts may be subject to completing the Texas Ethics Commission's Local Government Officer Conflicts Disclosure Statement.
- The [Office of Grants Development and Compliance](#) will forward to the IRB any financial interest disclosures received in connection with proposals for extramural funding that involve human subjects.

X. Research Misconduct Process

According to the [Office of Research Integrity of the U.S. Department of Health and Human Services \(ORI\)](#) and the [Office of Investigations of the National Science Foundation \(NSF\)](#), research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in

reporting research results:

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, processes or changing or omitting data or results such that the research is not accurately represented in the research record.
- Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

In addition, intellectual property permission related to ownership of ideas, concepts and protocols must be followed. Research misconduct does not include honest error or differences of opinion. The NSF requires a grantee to bear primary responsibility for prevention and detection of misconduct. NSF will rely on a grantee to take the following actions promptly: (a) Initiate an inquiry into any suspected or alleged misconduct; (b) Conduct a subsequent investigation, if the inquiry finds substance; (c) Take action necessary to ensure the integrity of research, the rights and interests of research subjects and the public and the observance of legal requirements or responsibilities and (d) Provide appropriate safeguards for subjects of allegations as well as informants. TCCD promotes the importance of and has procedures for referring to TCCD's General Counsel any potential incidents of research misconduct reported for resolution according to procedures identified in the Code of Federal Regulations 45 CFR 689 (for NSF) or 42 CFR Parts 50 and 93 (for the Department of Health and Human Services(HHS)).

If a grantee wishes NSF to defer independent inquiry or investigation, it should take the following actions:

1. Inform NSF immediately if an initial inquiry finds substance.
2. Keep NSF informed during such an investigation.
3. Notify NSF even before deciding to initiate an investigation or as required during an investigation:
 - a) If there is reasonable indication of possible violations of civil or criminal law.
 - b) If public health or safety is at risk.
 - c) If NSF's resources, reputation, or other interests need protection.
 - d) If federal action may be needed to protect the interests of a subject of the investigation or of others potentially affected.
 - e) If the research community or the public should be informed.
 - f) If research activities should be suspended.
4. Provide NSF with the final report from any investigation.

In order to implement federal research misconduct regulations, the TCCD Office of Grants Development and Compliance will implement the following procedures:

1. Post federal research misconduct regulations and information on the website of the Office of Grants Development and Compliance.
2. Communicate with and provide training to grant-funded PIs, Co- PIs, and Senior Personnel appropriate federal policies and TCCD procedures relating to research misconduct.
3. Require grant-funded PIs, Co- PIs to certify during the proposal transmittal process that they:
 - a) Have read and understand federal research misconduct regulations.
 - b) Will not engage in fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results.
 - c) Will report any suspected incidents of research to the Associate Vice Chancellor of Grants Development and Compliance or the TCCD General Counsel.

XI. Procedures of the IRB

A. IRB Research Reviews

Research is classified as either Minimal Risk or Greater than Minimal Risk.

1. 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 the subjects' daily life or during the performance of routine physical or psychological examinations or tests.

2. Greater than Minimal Risk (GMR) refers to research activities that do not meet the definition of “Minimal Risk.”

The IRB Chair may recommend a proposal to the IRB for: (a) expedited review, (b) expedited review pending recommended changes/clarifications or (c) review by the full Board. The IRB Chair cannot disapprove of a proposal but may defer action pending further information/clarifications. The IRB Chair will inform the PI of its actions. Any disagreement between the PI and the IRB Chair must be resolved by the full Board.

Exempt Research - Categories

Under federal regulations, certain types of research are exempt from federal policy unless the appropriate federal agency heads have determined otherwise.

- (1) Exempt Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
 - (i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111.
- (3)
 - (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
 - (A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
 - (B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
 - (C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by § 46.111(a)(7).
 - (ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find

the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

- (4) Secondary research for which consent is not required: Secondary research uses of identifiable confidential information or identifiable biospecimens, if at least one of the following criteria is met:
- (i) The identifiable confidential information or identifiable biospecimens are publicly available;
 - (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
 - (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or
 - (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the [E-Government Act of 2002, 44 U.S.C. 3501](#) note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the [Privacy Act of 1974, 5 U.S.C. 552a](#), and, if applicable, the information used in the research was collected subject to the [Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.](#)
- (5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the [Social Security Act](#), as amended.
- (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.
 - (ii) [Reserved]
- (6) Taste and food quality evaluation and consumer acceptance studies:
- (i) If wholesome foods without additives are consumed, or

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

The IRB Chair, not the investigator, shall make the determination as to whether a project is or is not exempt.

Expedited Research - Categories

Under federal regulations certain types of research qualify for an Expedited Review Categories. These activities: present no more than minimal risk to human subjects and involve only procedures specified in federal regulations. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on the list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. The list of categories of research that may be reviewed by the IRB through an expedited review is as follows:

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:
 - a) 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
 - b) from other adults and children [2], 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: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) 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; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) 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; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) 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: (a) 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; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) 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). (**Note:** Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
 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, or oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (**Note:** Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)
 8. Continuing review of research previously approved by the convened IRB as follows:
 - a) where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
 - b) where no subjects have been enrolled and no additional risks have been identified; or
 - c) where the remaining research activities are limited to data analysis.
 9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

[1] An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110. [2] Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." 45 CFR 46.402(a). Source: 63 FR 60364-60367, November 9, 1998.

Full IRB Committee Review

More Than Minimal Risk - If the proposed research does not qualify for Exempt or Expedited Review as defined above, it will be subject to a Full Review. Protocols requiring Full Review are vetted by the entire IRB and discussed at a convened meeting.

Proposals for full Board review should be submitted a **minimum of 30 days** in advance. The prospective PI will submit to the IRB an IRB Research Proposal form to irb@tccd.edu. In the Petition, the PI(s) assures the IRB that the principles, procedures, and guidelines established in the present document will be followed and agrees to provide the IRB access to pertinent records or research. In addition, the investigator should present any information that will aid in evaluating the proposal for compliance with this policy. The PI must be available to discuss the proposal and/or consent forms at the discretion of the IRB.

In addition, all proposed research proposal involving any of the following, it will be subject to Full Review.

- Children under the age of 18.
- Prisoners.
- Individuals with impaired decision-making capacity.
- Economically or educationally disadvantaged persons.
- Procedures that might cause physical harm.
- Procedures that might cause significant psychological/emotional distress.
- Collection of information about sensitive topics.
- Collection of information about illegal behavior.
- Collection of information that could seriously harm the participant legally, socially, financially etc. if other people could identify them.

Prospective Principal Investigators (PIs) seeking an exemption or an expedited review must submit an IRB Research Proposal Form to the IRB Chair via email irb@tccd.edu along with:

1. **Signed** finalized IRB research study approval document from your degree granting institution.
2. **Approved** finalized copy of your research proposal. This should be chapter 1 of your proposal, the Introduction (includes the statement of the problem, purpose/significance of the study, hypothesis, methodology, research questions, scope, conceptual/theoretical framework, assumptions-delimitations-limitations, definition of terms used and summary).
3. **Signed** Site approval letter.
4. **Completion** of HRS Training Certification/Documentation.
5. Informed Consent Document.
6. Any Recruiting Materials (Flyers, emails, etc.). What is expected of the participant? The time commitment. The location where the research will take place.).
7. Data Instruments (survey(s), questionnaire(s), interview guides(s)).
8. Any of the below forms when applicable to the nature and scope of the proposed research:
 - Adverse Event.
 - Ethnographic Fieldwork.
 - Off-Site Location.
 - Other IRB Authorization Agreement.
 - Research Study Modification Request.
 - Use of Deception.
 - TCCD Faculty Advisor Assurance Form.
 - Vulnerable Populations Protocol Form Minors (e.g., children (Under 18), pregnant women*, fetuses, neonates, prisoners (Individuals involuntarily detained), individuals with impaired decision-making capacity or who are economically or educationally disadvantaged).

Continuing Research Review Request

An Institutional Review Board (IRB) must review research proposals at least annually, or more frequently if the IRB determines it is necessary, until the research is complete. This continuing review ensures the research continues to meet ethical standards and protects the rights and welfare of participants.

The investigator must submit a Continuing Research Request Form **45 days** in advance of the annual date or approved research end date, along with the additional information stipulated on the form. If an investigator fails to submit the form to the IRB or the IRB has not reviewed and approved a research study, the research must stop, unless the IRB Chair or Vice Chair find that it is in the best interests of individual subjects to continue participating in the research interventions or interactions, and this finding is ratified at the next convened IRB meeting.

Allowing a protocol to expire is considered non-compliance. The proposal will be considered closed and no human subject research activities (i.e., enrollment of new subjects, any data collection) may occur until approval is secured.

HHS regulations set forth the criteria for IRB approval of research (45 CFR 46.111, 46.204-207, 46.305, and 46.404-409). In order to re-approve research at the time of continuing review, the IRB must determine that all of following requirements are satisfied:

- Risks to subjects are minimized (i) by using procedures which are consistent with sound research design, and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes (45 CFR 46.111(a)(1)).
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to the subjects and the importance of the knowledge that may reasonably be expected to result (45 CFR 46.111(a)(2)).
- Selection of subjects is equitable (45 CFR 46.111(a)(3)).
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, and appropriately documented in accordance with, and to the extent required by, HHS regulations at 45 CFR 46.116 and 46.117, respectively (45 CFR 46.111(a)(4) and (5)).
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects (45 CFR 46.111(a)(6)).
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (45 CFR 46.111(a)(7)).
- Appropriate safeguards are included to protect subjects likely to be vulnerable to coercion or undue influence (45 CFR 46.111(b)); and
- When the research involves pregnant women, fetuses, or neonates; prisoners; or children, the research satisfies the additional requirements for IRB approval under HHS regulations at subpart B, C, or D, respectively, of 45 CFR part 46.

The IRB should focus on whether there is any added information provided by the investigator, or otherwise available to the IRB, which would alter the IRB's prior determinations, particularly with respect to the IRB's prior evaluation of the potential benefits or risks to the subjects. The IRB also should assess whether there is any added information that would necessitate revision of the protocol and/or the informed consent document. IRBs have the authority to disapprove or require modifications in (to secure re-approval of) a research activity that does not meet the above criteria (45 CFR 46.109(a)). If research does not satisfy all of the above criteria, the IRB must require changes that would result in research satisfying these criteria, defer action, or deny the research proposal.

A Continuing Research Request form is to be completed and returned to the IRB Chair along with:

1. Copy of current Human Subjects Testing Training Certificate.
2. Current Informed Consent form and updated informed consent.
3. Original proposal and any proposal updates or modifications – which requires a Study Modifications Request form to be submitted).
4. Progress Report.
5. Problem Summary Sheet.
6. Adverse Event form (if applicable).

When a Continuing Research Request form is submitted, the IRB Chair shall consider the following:

- Changes to the research, proposal deviations, and violations since the last scheduled review.
- Adverse event reports.
- Reports of unanticipated problems involving risks to subjects and, if available.

- Data safety monitoring reports. If the proposal and/or other documents used in the project have been amended, the PI will be requested to submit a new proposal incorporating these amendments if such has not previously been submitted.

B. Actions of the IRB

The IRB may take one of the following four actions in regard to the proposed proposal and consent form: approved, approved with conditions/restrictions, deferred – requires revisions/clarifications or denied.

1. Proposal Approved

All of the following requirements must be met before research involving human subjects can be approved.

- Risks to subjects are minimized through sound research design that avoids unnecessary exposure and, when appropriate, by using procedures already being performed for diagnostic or treatment purposes.
- Risks are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge expected to result.
- Selection of subjects is equitable.
- Special consideration must be given when involving vulnerable populations, including children (Under 18), pregnant women*, fetuses, neonates, prisoners (Individuals involuntarily detained), individuals with impaired decision-making capacity or who are economically or educationally disadvantaged.
- Informed consent is obtained from each prospective subject or legally authorized representative in accordance with federal guidelines. Additional information may be required if necessary to protect subjects' rights and welfare.
- Documentation of informed consent follows federal requirements.
- When appropriate, the research plan includes provisions for monitoring collected data to ensure subject safety.
- When appropriate, provisions are in place to protect subject privacy and maintain confidentiality. Additional safeguards are required for subjects vulnerable to coercion or undue influence.

Additional Considerations for Proposal Approval

1. The proposal clearly demonstrates protection of subjects' rights in its design and procedures.
2. Adequate debriefing is assured, with subjects given explanations following participation.
3. Immediate debriefing is strongly recommended unless delayed disclosure is necessary to protect data integrity.
4. Facilities and resources are adequate to complete the study and protect subjects' rights.
5. Anticipated benefits, if any, are clearly stated.
6. Personal risks to subjects are reasonable in relation to expected benefits.
7. Procedures for securing informed consent are adequate.
8. Measures for minimizing risk and protecting subjects' health, safety, comfort, and legal rights are sufficient.
9. Measures for protecting subject privacy and data confidentiality are adequate.

Once a proposal has been approved, the Principal Investigator (PI) will receive an IRB Approval Cover Letter via email. The PI is responsible for sharing this approval document with relevant parties, such as the dean(s), director(s), or faculty sponsor, to confirm that the research study has undergone IRB review and received formal approval.

2. Proposal Approved with Conditions/Restrictions

In the course of initial or continuing review of research, or review of proposed changes to previously approved research, IRBs often request that investigators (a) make specified changes

to the research protocols or informed consent documents; or (b) submit clarifications or additional documents (c) confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted.

If the proposal is approved with conditions, the Chair will notify the PI in writing, outlining the conditions. The PI must respond to the conditions as indicated by the IRB. Upon receipt and approval of the responses, the conditions are removed, and the research study is then processed as an approved study and distributed as described above.

3. **Proposal Deferred – Requires Revisions/Clarifications**

Deferred action means that the submitted proposal was not sufficiently complete for the IRB to reach a final decision. In this case, the PI is notified by an IRB member, and the additional information necessary for completion of the IRB review is requested. In the case of a deferred proposal, the PI may be invited to attend an IRB meeting to present/clarify the proposal for the Board.

4. **Proposal Denied**

If the proposal is denied, the PI will be informed in writing of the reasons for the denial. The PI may revise and resubmit his/her proposal for another review.

The IRB attempts to review proposals within four weeks of their receipt. Proposals submitted during the summer or during TCCD holidays may be delayed. Because proposals may require revisions before IRB approval, researchers should allow sufficient time for the IRB to evaluate the revised submission. TCCD's IRB meets on an as needed basis, and meetings can be conducted in person or via telephone conferences.

The PI will be notified by email of the IRB decision by the Chair. If it is determined that the proposal requires a full IRB review, the proposal will be returned to the PI, with comments, for revision and submission to the full board. Upon receipt of the material from the PI, the IRB Chair will distribute copies to each IRB member. The federal guidelines stipulate that IRB approval is granted for a maximum of one year, and continuing reviews must be conducted annually (or more frequently, depending on the risks involved) to ensure the ongoing protection of human subjects involved in research.

C. **Proposal Review Procedures**

1. The IRB shall have authority to determine which studies need verification from sources other than the investigators, particularly:
 - a) Complex projects involving unusual levels or types of risk to subjects.
 - b) Projects conducted by investigators who previously have failed to comply with the requirements of the HHS regulations, or the requirements or determinations of the IRB.
 - c) Projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.
2. PIs should be informed at the time of proposal approval (both initial and continuing) that changes/modifications in approved research proposals may not be initiated without IRB review and approval, except where necessary to eliminate apparent immediate hazards to subjects.
3. PIs should be informed at the time of proposal approval (both initial and continuing) that any serious or on-going problems are to be reported promptly to the IRB.
4. Serious or continuing noncompliance by an investigator, or any suspension or termination of activities, is to be reported promptly to the IRB Chair so that appropriate remedial action can be taken, including, but not limited to, appropriate reporting to the granting agency.

D. **Adverse Event Reporting Guidance**

OHRP recognizes that any adverse event in a trial is a potentially important occurrence because it may reflect additional risks to subjects. In accordance with their requirements, these regulatory

bodies have charged IRBs with the responsibility of conducting continuing review of research. Included in this review is the monitoring of adverse reactions and unexpected events (21 CFR 56.108 and 45 CFR 46.103).

PI(s) and any TCCD employee will submit an Adverse Event Report to the IRB Chair any of the following upon knowledge of such.

Unanticipated problems involving risks to subjects or others that are:

- Unexpected in nature, severity, or frequency.
- Related or possibly related to the research.
- Suggest increased risk to participants or others.
- Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

These may require protocol changes, modified consent documents, or suspension of study activities. Some unanticipated problems involve non-physical harms (e.g., social, or economic) and must still be reported. Not all adverse events qualify as unanticipated problems. To meet reporting criteria under HHS regulations, an adverse event must also: be unexpected, be related or possibly related to participation, indicate greater risk than previously recognized.

E. Vulnerable Populations Guidance

Vulnerable populations include those whose diminished autonomy compromises their ability to give informed consent to participate in research. Children, pregnant women, fetuses, people with intellectual disabilities, prisoners, and the economically or educationally disadvantaged are among the groups most often identified as being vulnerable. However, depending on the context of the research or other circumstances, numerous other groups may also be considered vulnerable. As a rule, anyone in a situation where his or her ability to give informed consent is compromised or eliminated should be considered vulnerable. At the time of IRB review, each research study is evaluated for the possibility of enrolling vulnerable populations. The IRB shall evaluate the risks and benefits of the research and ensure that the consent form properly conveys the nature, magnitude and probability of the risks and benefits clearly and accurately. The IRB will review the recruitment and consent processes to ensure that subjects are properly informed and not misled. The IRB will determine if additional safeguards are required. If regulations allow, it will also determine if the risks warrant the ability for the study to be reviewed by expedited review at future renewals.

Approval for research studies involving vulnerable populations is considered if one of the following conditions is met:

- The research does not involve more than minimal risk to the participant.
- The research is likely to benefit the participant directly, even though the risks are considered to be more than minimal.
- The research involves greater than minimal risk with no prospect of direct benefit to individual participants but is likely to yield generalizable knowledge about the participant's disorder or condition.

Vulnerable Populations Identified by Federal Regulations

- Pregnant Women, Human Fetuses and Neonates Involved in Research (45 CFR 46, Subpart B). Special regulatory requirements govern the participation of pregnant women in research [45 CFR 46 Subpart B]. Research involving women who are or may become pregnant receives special attention from IRBs because of women's additional health concerns during pregnancy and because of the need to avoid unnecessary risk to the fetus.
- Research Involving Prisoners as Subjects (45 CFR 46, Subpart C). Research involving prisoners is highly regulated due to ethical concerns over potential coercion and exploitation. In the United States, federal regulations (45 CFR 46, Subpart C) classify prisoners as a "vulnerable population" requiring special protections. These protections are designed to ensure that any participation is voluntary and that risks are minimized.

- Children Involved as Subjects in Research (45 CFR 46, Subpart D).
Children are considered a vulnerable research population because their emotional and intellectual capacities may be limited, and they are not of a legal age to give informed consent.

In addition to those specified in federal regulations, the IRB considers other groups that may require additional protections. Vulnerability may vary by institution and study. Populations needing special consideration include:

- Acutely Ill Individuals – Limited capacity for informed consent due to urgent medical needs.
- Decisionally Impaired Individuals – Capacity must be assessed before and during research; surrogate consent may be permitted under IRB-approved circumstances.
- Economically Disadvantaged Persons – Risk of undue influence due to compensation or access to otherwise unaffordable care.
- Educationally Disadvantaged Persons – Limited ability to read or comprehend study information.
- Elderly/Aged Persons – Potential cognitive decline and increased sensitivity to risks.
- Incapacitated Persons – Vulnerability due to illness, injury, sedation, or substance use.
- Individuals with Handicaps – Physical or sensory impairments may affect comprehension.
- Minorities – Cultural norms and language barriers may limit decision-making capacity.
- Students and Employees – Possible coercion due to authority relationships.
- Terminally Ill Patients – Require protection against undue influence but should not be excluded when participation is relevant and voluntary.

XII. Operations of the IRB

A. IRB Meetings

- The IRB meets monthly Fall, Spring, and Summer semesters.
- Meetings are held on campus and via TEAMS.
- Agenda and study material to be reviewed are distributed to IRB members at least seven (7) days prior to the meeting.

B. IRB Reviewers

The IRB Chair assigns one primary reviewer and at least one secondary reviewer for each new full research review. The primary reviewer is assigned consistent with proposal content and reviewer expertise. Secondary reviewer(s) may be assigned using additional factors such as their ability to provide a valuable perspective on salient non-scientific aspects of the research. The reviewers, who are assigned, based on their expertise, lead the discussion of that proposal. Other IRB members review summary information only but have access to complete study documentation upon request. If external reviewers are also assigned, they must be subject to the same conflict of interest policies as IRB members.

C. Voting Requirements

1. Except when an expedited review procedure is used, a quorum of the IRB, duly convened through written notice, shall be a majority of voting members with varying backgrounds to promote complete and adequate review of research activities, including at least one member whose primary concerns are in nonscientific areas.
2. In order for the research to be approved, it shall receive the approval of a majority of those voting members present at the meeting. IRB meetings conducted via telephone conference call are permitted pursuant to OHRP guidelines.
3. PIs, including those who are also IRB members, may offer information and answer questions about their proposals at a convened meeting but may not be present during voting (even if this means being unable to continue the meeting because of quorum requirements).
4. Although convened meetings of the IRB are open to the public, materials submitted for review, discussions of proposal and individual votes are considered confidential and should not be discussed outside of the meeting context. If during an IRB meeting the Chair moves the meeting to an executive session, then any visitors will be asked to leave the room until the executive session has ended.

D. Appeals

The Principal Investigator (PI) may appeal the decision of the IRB when a proposal has been disapproved or approved subject to restrictions and mutual agreement cannot be reached as to an acceptable alternative. Upon written notification of appeal from the PI, the IRB shall name an ad hoc committee of three or more faculty and/or consultants to review the proposal a second time. The ad hoc committee members must be acceptable to both the PI and the IRB. The proposal will be reviewed in accordance with the guidelines established herein and the decision of the ad hoc committee will be referred to the IRB. The PI will be promptly notified of actions of the ad-hoc committee and ultimate action by the IRB. Final disapproval of the IRB cannot be overridden by any institutional official.

E. Amendments/Significant Modifications

Modifications to research studies require review and approval unless there is an immediate need to eliminate a hazard to subjects. Modifications can range from minor changes like updating contact information to major changes like altering the study protocol or adding new procedures. Any change that affects the study protocol, consent forms, or participant risk must submit Study Modification Request form to the IRB for review and approval before implementation.

1. Categories of amendments/modifications.

- a) **Minor Changes:** A proposed change in research-related activities that does not significantly affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study.

Examples of minor changes to a research study include, but are not limited to, the following:

- (1) Addition or deletion of study team members.
- (2) Addition of procedures that do not significantly increase risk to subjects, considering the original purpose and study design of the approved study.
- (3) Removal of research procedures that would thereby reduce the risk to subjects.
- (4) Addition of nonsensitive questions to unvalidated survey or interview procedures.
- (5) Addition of or revisions to recruitment materials or strategies.
- (6) Administrative changes to the approved documents (e.g., correction of spelling, grammatical or typographical errors).

- b) **Significant modification/change:** A proposed change in research-related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study.

Examples of significant changes to a study may include, but are not limited to, the following:

- (1) Addition of a new and/or separate subject population (e.g., control group, additional cohort, vulnerable population, etc.).
- (2) Addition of research procedures that involve greater than minimal risk to subjects.
- (3) Addition of surveys/questionnaires/interview procedures that could have adverse psychological consequences for subjects or damage their financial standing, employability, insurability, or reputation.
- (4) Removal of follow-up visits that appear necessary for monitoring a subject's safety and welfare.

- c) **Level of Review for Amendments/Modifications:** Significant modifications will generally be reviewed at the same level of review in which the study was first reviewed, either by the screening committee or by the full IRB. However, if an amendment by the screening committee is determined to increase the level of risk beyond minimal risk, the screening committee will refer to the amendment to the full IRB. Minor modifications may be reviewed and approved using an administrative approval process. Such approvals are then put on the agenda of the next IRB or screening committee, as appropriate, for concurrency.

- d) **Sponsor Agency Modifications:** Modifications can be made only to IRB-approved studies. A sponsor agency may modify the research proposal before the study has received final approval from the IRB. If this occurs, it is recommended that investigators await receipt of the IRB approval letter before making changes to the research proposal. Sponsor agency-

generated modifications (or addenda) require review and approval by the IRB or Screening Committee, as appropriate. The PI should provide all sponsor documentation and summarize how the changes affect the approved proposal, recruitment, enrollment, treatment, and follow-up of participants.

F. Grievances

The IRB shall be informed of all grievances (e.g., of a research subject against a PI) and, if requested, the IRB will act in an advisory capacity.

G. Cooperative Activities

Cooperative activities relating to human subjects are those which involve TCCD and another institution. Normally, the research must be reviewed and approved by the IRBs at both institutions before it can be initiated. However, the IRB of one institution may rely on the IRB of the other institution under the following conditions:

- Both institutions have FWAs approved by OHRP.
- Both institutions have entered into an Authorization Agreement (or equivalent document) that stipulates the responsibilities of both parties.
- The appropriate section of the FWA of the deferring institution designates the IRB of the approving institution.

In the absence of these conditions, the PI must secure the approval of the IRB at each institution engaged in the research and submit documentation of such approvals to the other IRBs. The IRB Chair will verify (via the OHRP website) that the other institutions have approved FWAs.

Key points about other IRB Authorizations

- Avoids duplicate review: This helps avoid duplicate IRB regulatory review when multiple IRBs would otherwise have authority for the same multi-site research protocol.
- Formal Agreement: The agreement is a formal document signed by the involved institutions, outlining the responsibilities and authorities of both the reviewing IRB and the relying institution(s).
- Types of Agreements: While "IRB Authorization Agreement" is a common term, these agreements can also be called Reliance Agreements, Cooperative Agreements, Memorandums of Understanding (MoUs), or Master Reliance Agreements (MRAs).
- Not a substitute for FWA: It is crucial to understand that IRB authorization agreements are not a substitute for or replacement of Federalwide Assurances (FWAs). All federally funded non-exempt human subjects research still needs to be conducted under an FWA, and the IRB is a component of that assurance.
- Mandatory for Federally Funded Research: As of January 2020, federally-funded, non-exempt research involving multiple institutions is required to be reviewed by a single IRB.

H. Record Requirements

The IRB prepares and maintains adequate documentation of IRB activities, including the following:

- Electronic copies of all research proposals: reviewed, approved sample consent documents and continuing reports submitted by PIs.
- Minutes of IRB meetings, showing the following:
 - Members present (any consultants/guests/others shown separately).
 - Results of discussions on debated issues and record of IRB decisions.
 - Record of voting (showing votes for, against and abstentions).
 - Records of continuing review activities updated consent documents and summaries of on-going project activities.
- Copies of all correspondence between IRB and the investigators.
- Any statements of significant new findings (unanticipated risks or adverse reactions) provided to subjects.
- Adverse reactions reports and documentation that the IRB reviews such reports.
- Emergency use reports.
- General project information provided to subjects (e.g., fact sheets, brochures). These

documents and records shall be retained for at least three (3) years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the:

- Department of Health and Human Services.
- Food and Drug Administration.
- Department of Veterans Affairs.
- Other federal regulatory agencies, at reasonable times and in a reasonable manner.

In addition, the IRB maintains a permanent record of the list of current IRB members, written procedures for the IRB and self-assessments. All forms submitted or retained as evidence of informed consent must be preserved by the PI for 3 years.

I. Information the Principal Investigator (PI) Provides to the IRB

1. Final IRB Approval (required for doctoral research) from your degree-granting institution.
2. Complete study proposal (This should be chapter 1 of your proposal, the Introduction (includes the statement of the problem, purpose/significance of the study, hypothesis, methodology, research questions, scope, conceptual/theoretical framework, assumptions-delimitations-limitations, definition of terms used and summary).

Include/address the following:

- Title of the study and summary of the research to be conducted.
 - The purpose of the study (including the expected benefits obtained by doing the study and how risks are reasonable in relation to expected benefits).
 - Sponsor of the study.
 - Subject inclusion/exclusion criteria (including scientific and ethical reasons for excluding subjects who might otherwise benefit from the research).
 - Justification for use of any special/vulnerable subject populations such as children (Under 18), pregnant women, fetuses, neonates, prisoners (Individuals involuntarily detained), individuals with impaired decision-making capacity or who are economically or educationally disadvantaged. (requires Vulnerable Populations Protocol form).
 - Study design (including discussion of the appropriateness of research methods).
 - Description of procedures to be performed.
 - Provisions for managing adverse reactions.
 - Circumstances surrounding consent procedure, including setting, subject autonomy concerns, language difficulties, and vulnerable populations.
 - Procedures for documentation of informed consent, including any procedures for obtaining assent from minors (minor' is defined in Texas as an individual under the age of 18), using legally authorized representatives, witnesses, translators, and document storage.
 - Remuneration to subjects for their participation.
 - Any compensation for injured research subjects.
 - Provisions for protection of subject's privacy.
 - Extra costs to subjects for their participation in the study.
 - Inclusion/exclusion of women, minorities, and/or children.
3. Approved site permission documentation.
 4. Evidence of Completion of Completed Human Subjects Testing Training.
 - a) Office for Human Research Protection (OHRP) offers a variety of free online trainings for the research community on human research protections based on the principles of the Belmont Report and the requirements of the revised Common Rule (or 2018 Requirements).
 - (1) Courses are comprised of modules that include: Human Research Protection Foundational Training, Considerations for Reviewing Human Subjects Research, OHRP Webinars and Mini-Tutorials.
 - (2) Training is free of charge.
 - (3) Trainings certificates are valid for 3 years and may be renewed by taking the training again.

- b) The Collaborative Institutional Training Initiative (CITI Program) CITI Program offers training in a variety of areas including research design and ethics, compliance, safety, and professional development.
- (1) Courses are comprised of modules that include detailed content, images, supplemental materials (such as case studies), and a quiz. Learners may complete the modules at their own pace. Each module varies in length. In general, modules can take about 30 to 45 minutes to complete.
 - (2) There is a fee for CITI training courses.
 - (3) Trainings certificates are valid for 3 years and may be renewed by taking the training again.
- c) The Association of Clinical Research Professionals (ACRP) offers a Certified Principal Investigator course.
- (1) The CPI® exam consists of 125 multiple choice questions that must be answered within 180 minutes.
 - (2) There is a fee for ACRP training courses.
 - (3) Trainings certificates are valid for 2 years and may be renewed by taking the training again.
5. Professional qualifications to do the research (including a description of necessary support services and facilities).
6. Appropriate TCCD forms:
Research Study Proposal form covering:
- Conflict of Interest Form.
 - Misconduct Form.
 - Consent Form and Checklist.
 - Principal Investigator Cover Sheet.
 - Principal Investigator Assurance Form.
- The following forms must be submitted when applicable to the nature and scope of the proposed research:
- Adverse Event Report Form.
 - Ethnographic Fieldwork Documentation.
 - Faculty Advisor Assurance Form.
 - Off-Site Research Location Approval.
 - Other IRB Authorization Agreement (for multi-site studies).
 - Research Modification Request Form.
 - Use of Deception Justification Form.
 - Vulnerable Populations Protocol Form (e.g., children (Under 18), pregnant women, fetuses, neonates, prisoners (Individuals involuntarily detained), individuals with impaired decision-making capacity or who are economically or educationally disadvantaged.)
7. Investigator's brochure (when one exists).
8. The case report form (when one exists).
9. Consent Forms: Informed/Assent - The proposed informed consent document, including translated consent documents, as necessary, considering subject population(s) or request for waiver of the requirement to obtain informed consent. The Principal Investigator is responsible for retaining informed consent documents for a period of three years after the project.
10. Copies of Proposal Recruitment Materials/survey tool/questionnaire/advertisements provided to subjects.

The IRB reviews recruitment methods and materials with respect to the research purpose, study setting, and participant population. Investigators should address the following ethical considerations, which also guide IRB evaluation:

- Equitable selection: Recruitment should ensure fair and appropriate participant selection based on clear inclusion and exclusion criteria (e.g., study variables, contraindications, safety concerns).

- Respect for persons: Recruitment must safeguard vulnerable populations (e.g., children (Under 18), pregnant women, fetuses, neonates, prisoners (Individuals involuntarily detained), individuals with impaired decision-making capacity or who are economically or educationally disadvantaged.)
- Freedom from pressure: Recruitment should allow participants sufficient time and choice, without undue influence from authority figures, timing, or excessive incentives.
- Respect for privacy: Recruitment must protect individuals' privacy and use confidential information only with permission. Screening should occur in private settings.
- Presentation of information: Recruitment materials must be accurate, balanced, and appropriately detailed, avoiding misleading or overly persuasive content.

Recruitment materials should contain the following key elements:

- Study title.
- The word "research." Make it clear that this is a research study and avoid coercive or unduly influential language.
- The PI's name and contact information.
- Eligibility inclusion/exclusion criteria, if applicable, should be noted briefly.
- State whether participants will be paid for their time and effort.
- Voluntariness of participation.
- Purpose of the study.
- What is expected of the participant?
- The time commitment.
- The location where the research will take place.

Types of Recruitment Materials: IRB review applies to virtually any material used to solicit participation in research.

Examples include:

- Posters and flyers.
 - Emails and letters.
 - Social media posts.
 - Website postings.
 - Advertisements (print, radio, or television scripts).
 - Verbal scripts for in-person or word-of-mouth recruitment.
11. Copies of relevant grant applications (if any).
 12. Any additions or changes in procedures in the proposal will be submitted to the IRB for written approval prior to changes being implemented. The submission of a Study Modification Request form is required whenever any changes are made and require approval before implementation.
 13. This includes, but is not limited to, changes in title, investigators, funding source, data collection methods, recruitment materials, confidentiality measures, or test instruments.
Note: All changes must be submitted and approved by the IRB **prior** to their implementation unless the change is necessary to protect the safety of participants.
 14. Any unexpected adverse events and unanticipated problems connected with the use of human subjects once the project has begun must be communicated to the IRB Chair. Unanticipated problems involving risks to subjects or others that are:
 - Unexpected in nature, severity, or frequency.
 - Related or possibly related to the research.
 - Suggest increased risk to participants or others.
 - Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.

15. Progress/interim reports that include reports of proposal violations and/or deviations and any other instances of investigator non-compliance.
16. The Principal Investigator shall notify the TCCD IRB chairperson when the research proposal has been approved or modified by another institution's IRB.
17. The Principal Investigator will provide a copy of the final research results to TCCD's IRB and complete the IRB's Research Closure form.

XIII. Research Consent

A. Principles of Informed Consent

1. When an activity does not involve therapy, diagnosis or management, and a professional/subject relationship exists, e.g., participation in a research project, the subject is entitled to certain information. This information includes a full and frank disclosure of all the facts, probabilities, options, and opinions which a reasonable person might be expected to consider before giving his/her consent. A copy of the signed consent form must be given to the person signing the form and a copy must be kept on file with the investigator or TCCD as indicated.
2. The informed consent of subjects will be obtained by methods that are adequate and appropriate. Consent must be obtained from the subjects themselves except when the subjects are not legally capable of giving informed consent because of age, or mental inability to communicate. In the case of a minor, the IRB may accept the permission of the minor's parents (or parent) or legal guardian, along with the assent of the minor, in accordance with applicable federal regulations. In the case of other subjects not legally capable of giving informed consent, the IRB may accept the consent from a legally authorized representative (LAR). The LAR must be authorized either by the power of attorney or a court order.
3. Informed consent means ensuring that potential subjects and/or their LARs are fully informed of all aspects of their participation in a research project so as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion.
4. The IRB shall determine whether the consent is adequate in light of the risks to the subject and the circumstances of the research. The IRB shall also determine whether the information to be given to the subject or to qualified third parties, verbally or in writing, is a fair explanation of the procedure, its possible benefits, and its attendant hazards. Where debriefing procedures are considered as a necessary part of the research plan, the IRB will ascertain that any such debriefings will be complete and prompt. In addition, the language used should be clear and unambiguous with every attempt to eliminate technical terms and jargon (i.e., using lay language appropriate to the subject population).
5. If the IRB determines that the research involves more than minimal risk to subjects, a compensation for injury statement will be required in the consent form. This statement should clarify who is responsible for any costs associated with any medical treatments required or any personal compensation for injuries received as a result of participation in the research.
6. Some research may not impose on the rights and welfare of human subjects so as to make informed consent a requirement. Therefore, the IRB may choose to waive the requirement to obtain a signed consent form for some or all subjects in some cases when it finds either:
 - a) That the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
 - b) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases where the documentation requirement is waived, the IRB may require the PI to provide subjects with a written statement regarding the research (e.g., a cover letter).

Examples of such research where use of a cover letter is generally appropriate are collecting data by survey or interview.

Any waiver of documentation by the IRB must be based upon clearly defensible grounds. A request for a waiver of documentation by the PI must include justifiable reasons in the proposal. The IRB may also choose to approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents the following:

- (1) The research involves no more than minimal risk to the subjects.
 - (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects.
 - (3) The research could not practicably be carried out without the waive or alteration.
 - (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
7. Informed consent need not be based on full pre-study information. However, it is the responsibility of the IRB to set limits on the incompleteness of such information. Further, in those studies in which it is proposed to mislead the subjects during data collection, the IRB has the responsibility of assessing the degree to which this violates the rights of the subjects and then setting the limits for such procedures.

B. Types of Consent

1. **Informed Consent:** is the disclosure of a survey's purpose and process. Informed consent should be written at the 6th to 8th grade levels. Researchers must obtain the signed informed consent of participants prior to conducting their research. "Informed Consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research.

Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate." The form should provide the potential subject or Legally Authorized Representative (LAR) "the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information."

2. **Assent Consent:** Affirmative agreement by an individual not competent to give legally valid informed consent (e.g., a child or person who is cognitively impaired) to participate in research. For participants younger than 18 years of age, the researcher must obtain the signed informed consent of parents or legal guardian, and all reasonable attempts must be made to obtain each participant's assent, which is defined as the participant's agreement to participate in the study.

C. Guidelines for Writing Inform Consent Forms

The following list of topics that the Common Rule departments and agencies indicated generally would encompass the key information required to satisfy §_45 CFR 116(a)(5)(i):

- The fact that consent is being sought for research and that participation is voluntary.
- The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research.
- The reasonably foreseeable risks or discomforts to the prospective subject.
- The benefits to the prospective subject or to others that may reasonably be expected from the research.
- Appropriate alternative procedures or courses of treatments, if any, that might be advantageous to the prospective subject.

Informed consent must include the following in sequential order and in language which the participants can understand:

- Statement of purpose of the study.
- Brief description of methodology and duration of participant involvement.
- Statement of risks/benefits to the participants.
- Statement of data confidentiality.
- Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.
- An offer to answer any questions the participant may have.
- Contact information of all Principal Investigators and for TCCD's IRB irb@tccd.edu.
- Statement that participant is 18 years of age or older unless parent or legal guardian has given consent.

IX. Using Deception in Research

The use of deception in research is **not** prohibited by federal or TCCD regulations. Deception is defined as providing intentionally misleading information. Incomplete Disclosure, in the context of research, can be defined as withholding information about the real purpose of the research or giving subjects false information about some aspect of the research.