Research Study Proposal

Guidelines & Forms

Contents

Introduction 2
IRB Research Proposals 2
Research Classifications 3
Expedited Research Review 4
  Expedited Categories 4
Full IRB Committee Review 6
Continuing Research 7
IRB Conflict of Interest 7
Research Misconduct Process 8
Using Deception in Research 9
Faculty Advisor Assurance 9
Informed Consent 9
  Types of Consent Informed Consent 9
Location Site Permission Approval 10
Adverse Event Report 12
Ethnographic Research/Fieldwork 13
Offsite Locations - Research Performed at Non-TCCD Sites and Locations 13
Other IRB Authorization Agreement 13
Vulnerable Populations 13
  Vulnerable Populations: Minors (Children under the age of 18) 13
  Vulnerable Populations: Pregnant Women, Human Fetuses or Neonates 14
  Vulnerable Populations: Prisoners 14
  Other Vulnerable Populations 15
Research Closure Form 15
TCCD IRB Proposal Form 15

Introduction

Tarrant County College District (TCCD) supports scholarly activities by students, faculty, and staff, many of which involve human subjects. Research is defined as a systematic investigation designed to develop or contribute to general knowledge.

TCCD's Institutional Review Board (IRB) reviews human subjects research to ensure:

- Protection of participants' rights and welfare.
- Minimization of risk and maximization of potential benefits.
- Informed, voluntary participation.
- Ethical and regulatory compliance.

Research involving human subjects may not begin without IRB approval. Some activities, such as course-based projects, anonymous educational tests, or voluntary, non-identifiable surveys/interviews, may be exempt. The IRB's role is to review, approve, disapprove, or require modifications to proposals based on risk, informed consent, and confidentiality—not on the scientific merit of the research.

Criteria for IRB Proposal Approval

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

- Risks to subjects are minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and when appropriate, by using procedures that are already being performed on the subjects for diagnostic or treatment purposes.
- 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.
- Selection of subjects is equitable. Particular attention should be paid to the special problems of research involving vulnerable populations, such as: (a) children, (b) prisoners, (c) pregnant women, (d) persons with intellectual disabilities or (e) economically or educationally disadvantaged persons.
- Informed consent will be sought from each prospective subject or his legally authorized representative in accordance with official guidelines. Information given to subjects as part of informed consent must also conform to these guidelines. The IRB may require that additional information be given if in its judgment the information would meaningfully add to the protection of the rights and welfare of subjects.
- Documentation of informed consent will be carried out in accordance with federal guidelines.
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of the subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards must be included to protect the rights and welfare of those subjects.

Revised 2018 Common Rule or 2018 Revisions, became effective in January 2019.

IRB Research Proposals

An IRB research proposal is a detailed document submitted to an Institutional Review Board (IRB) for approval before a study involving human subjects can begin. The proposal outlines the study's purpose, methods, potential risks, and benefits to protect the rights and welfare of participants. The IRB, an ethics review committee, uses the proposal to ensure the research is scientifically sound, ethical, and complies with all federal and institutional regulations.

Proposals (typically Chapters 1, 2, and 3 of your dissertation) cover the following components:

- **Purpose and Methodology:** A clear description of the research goals, the questions the study will answer, and the specific procedures that will be followed. This section details how data will be collected and analyzed.
- **Participant Population:** A description of who will be involved in the study, including both inclusion and exclusion criteria. The proposal must explain how participants will be selected fairly and equitably.
- **Risks and Benefits:** An analysis of potential risks to participants and a justification for why these risks are reasonable compared to the potential benefits of the research.
- **Protection of Subjects:** A plan for how participant rights and welfare will be protected throughout the study, which must include adequate safeguards, especially for vulnerable populations.
- **Informed Consent:** A description of the process for obtaining informed consent, which includes providing participants with a clear, understandable form that details the study and their rights.
- **Recruitment Materials:** Any advertisements, flyers, or other materials used to recruit participants.
- **Data Collection Instruments:** Copies of all surveys, questionnaires, and other tools that will be used to collect data from participants.

Research Classifications

Research is classified as either Minimal Risk or Greater that 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 the subjects' daily life or during the performance of routine physical or psychological examinations or tests. Greater than Minimal Risk (GMR) refers to research activities that do not meet the definition of "Minimal Risk."

Exempt IRB Research Proposals

Under federal regulations, certain types of research are exempt from federal policy unless the appropriate federal agency heads have determined otherwise. Exempt research poses minimal or no risk to participants and falls into specific categories defined by federal regulations and does not require monitoring by the Institutional Review Board (IRB). Exempt categories are outlined by the Department of Health and Human Services in 45 CFR 46.101(b).

The significance of an exempt review is that the IRB does not monitor the research activity. It is important to note that while a project may be exempt from IRB regulations, the ethical principles of conducting human subject research still apply. More importantly, it is not up to the researcher to determine whether a project is exempt. Researchers that believe their project is exempt should submit their research proposal to the IRB, selecting exempt for their category of review. Exempt reviews are carried out by the IRB Chair or their designee. Examples of exempt research include research on normal educational practices or studies involving anonymous surveys with non-sensitive questions.

Exempt categories are outlined by the Department of Health and Human Services in 45 CFR 46.101(b).

1. **Educational Settings** - §46.104 (a)(d)(1). Research in standard educational settings involving normal practices that do not negatively affect student learning or teacher evaluation. This includes most studies on instructional strategies, curricula, or classroom methods.
2. **Tests, Surveys, Interviews, or Public Behavior** - §46.104 (a)(d)(2). Research involving educational tests, surveys, interviews, or observation of public behavior (including recordings) is **exempt if:**
   a. Subjects cannot be readily identified.
   b. Disclosure of responses would not harm the subject's legal, financial, or social standing.
   c. Identities can be determined, but a limited IRB review is conducted under §46.111(a)(7).
3. **Benign Behavioral Interventions** (Adults Only) - §46.104 (a)(d)(3).
   Research involving harmless, brief behavioral tasks (e.g., games, puzzles, decision- making), with prior consent, is **exempt if:**

   a. Subjects cannot be readily identified.
   b. Disclosure would not reasonably harm the subject.
   c. Identities can be determined, but a limited IRB review is conducted per §46.111(a)(7).
   d. Interventions must be non-invasive, not offensive, and have no lasting impact.
   e. If deception is used, it must be authorized in advance, and subjects must know they may be misled.
4. **Secondary Research Using Existing Data or Specimens** - §46.104 (a)(d)(4) is **exempt if:**
   a. Data or specimens are publicly available.
   b. Subjects cannot be identified, and there is no contact or re-identification.
   c. Use of identifiable health information is regulated under 45 CFR Parts 160 and 164 (e.g., HIPAA);or
   d. Conducted by/for a Federal agency using protected data under the E- Government Act, Privacy Act, and Paperwork Reduction Act.
5. **Federal Research or Demonstration Projects** - §46.104 (a)(d)(5).
   Exempt if funded or approved by a Federal agency to study, improve, or evaluate public benefit or service programs (e.g., benefits access, payment models).
   a. The project must be posted on a public federal website before research begins.
6. **Taste and Food Quality Studies** - §46.104 a)(d)(6) is **exempt if**:
   a. Wholesome foods without additives are tested; or
   b. Foods contain ingredients or contaminants at levels deemed safe by the FDA, EPA, or USDA.

For detailed regulatory language, see 45 CFR 46 Subpart A.

Expedited Research Review

Expedited review procedures are described in HHS regulations at 45 CFR 46.110. An expedited review is typically carried out by the IRB Chair or their designee and involves research that does not involve more than minimal risk to participants. Minimal risk is defined as: the probability and magnitude of harm or discomfort anticipated in the research are not greater than those encountered in daily life or through the performance of routine physical or psychological exams/tests. While the IRB Chair can review and approve expedited review research, the Chair cannot disapprove research proposals without moving the research project to full review.

Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) through an Expedited Review Procedure.

1. Research with no more than minimal risk and involving procedures listed below may be reviewed through the expedited procedure (45 CFR 46.110; 21 CFR 56.110). Inclusion on the list does not mean the activity is automatically minimal risk.
2. Categories apply regardless of subject age, unless noted.
3. Expedited review may not be used if subject identification could reasonably create legal, financial, employment, insurance, reputational, or stigmatizing risks, unless adequate protections reduce these risks to minimal.
4. Expedited review may not be used for classified research with human subjects.
5. Standard informed consent requirements apply to all reviews.
6. Categories (1)–(7) apply to both initial and continuing IRB review.

Expedited Categories

Category 1 - Research involving clinical studies of drugs and medical devices AND one of the following are true:

- The research is 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.)
- The research is on medical devices and either of the following are true:

  - An investigational device exemption application (21 CFR Part 812) is not required.
  - Or the medical device is cleared/approved for marketing, and the medical device is being used in accordance with its cleared/approved labeling.

Category 2 - Research involving the collection of blood samples by finger stick, heel stick, ear stick, or venipuncture AND either of the following are true:

- The blood is collected from healthy, non-pregnant adults who weigh at least 110 pounds. The amounts drawn do not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week.
- The blood is collected 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. 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.

Category 3 - Research involving the prospective collection of biological specimens for research purposes by noninvasive means. Examples include:

- Hair and nail clippings in a non-disfiguring manner.
- Deciduous teeth at time of exfoliation or 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 gum base or wax or by applying a dilute citric solution to the tongue.
- Placenta removed at delivery or 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.

Category 4 - Research involving the collection of data through noninvasive procedures routinely employed in clinical practice.

- Research NOT involving general anesthesia, sedation, x-rays, or microwaves.
- Research where medical devices are employed 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 of acceptable non-invasive procedures include:
  - 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.

Category 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 qualify for Exempt Registration under Category 4.

Category 6 - Research involving the collection of data for research purposes from one of the following: Voice recording; Video recording; Digital recording; Image recordings.

Category 7 - One of the following is true:

- 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).
- Research employing survey, interview, oral history, focus group, program evaluation human factors evaluation or quality assurance methodologies.

Note: Some research in this category may be Exempt Registration under Categories 2 and 3.

Category 8 - The continuing review of research previously approved by the full Committee. One of the following is true:

- The research is permanently closed to enrollment of new subjects; subjects completed all research-related interventions; research active only for long-term follow-up of subjects.
- No subjects have been enrolled, and no additional risks have been identified. Research activities are limited to data analysis.

Category 9 - The continuing review of research, NOT conducted under an investigational new drug application or investigational device exemption.

- Categories 2 through 8 do not apply **BUT** the full Committee has determined and documented that the research involves no greater that minimal risk and no additional risks have been identified.
    - Minimal risk is defined as where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily lives of the general population or during the performance of routine physical or psychological examinations or tests.

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.

- Minors (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.

Continuing Research

The IRB must review research at least annually, or more often if needed, until the study is complete. This review ensures ongoing compliance with ethical standards and participant protection. Investigators must submit a Continuing Research Request Form 45 days before the annual due date or study end date. Research must stop if the form is not submitted or the IRB has not approved the study, unless the IRB Chair or Vice Chair determines continuation is in the best interests of participants and this is confirmed at the next convened meeting. Letting a protocol expire is considered non-compliance; no human subject research activities may continue until approval is reinstated.

At continuing review, the IRB must confirm the following (45 CFR 46.111):

- Risks are minimized and reasonable in relation to potential benefits and knowledge gained.
- Subject selection is equitable.
- Informed consent is properly obtained and documented.
- Adequate monitoring ensures subject safety.
- Privacy and confidentiality protections are in place.
- Safeguards protect vulnerable populations.
- Additional requirements are met for research involving pregnant women, fetuses, neonates, prisoners, or children.

The IRB evaluates whether latest information affects prior risk-benefit determinations or requires protocol/ consent revisions. Research not meeting these standards may be modified, deferred, or disapproved. 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.

The PI will be notified of the action taken (e.g., Approved, Approved Subject to Restrictions, etc.) in writing. A Research Closure form is required to be submitted to the IRB when they have completed their research.

IRB 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.

Research Misconduct Process

According to the Office of Research Integrity of the U.S. Department of Health and Human Services 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.

NSF requires grantees to:

1. Promptly inquire into suspected misconduct.
2. Investigate if warranted.
3. Protect research integrity, participants, and legal obligations.
4. Safeguard both informants and those accused.

Post federal research misconduct regulations and information on the website of the Office of Grants Development and Compliance communicate with and provide training to grant-funded PIs, Co- PIs, and Senior Personnel appropriate federal policies and TCCD procedures relating to research misconduct. Require grant-funded PIs, Co-PIs to certify during the proposal transmittal process that they:

- Have read and understand federal research misconduct regulations.
- Will not engage in fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results.
- Will report any suspected incidents of research to the Associate Vice Chancellor of Grants Development and Compliance or the TCCD General Counsel.

For detailed regulatory language, see **Code of Federal Regulations - 45 C.F.R.§689.1**., **Public Health Service Policies on Research Misconduct Part 93,** and **U.S. Department of Health and Human Services, Office of Research Integrity** websites.

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.

Faculty Advisor Assurance

An IRB Faculty Advisor Assurance is a document signed by a faculty member at a university or institution, confirming they have reviewed a student's research proposal involving human subjects and will provide direct supervision, ensuring the student will conduct the research ethically and in compliance with IRB and federal regulations. The form serves as assurance that the faculty advisor accepts responsibility for guiding the student's project and monitoring the ethical treatment of human participants.

Informed Consent

Under HHS regulations (45 CFR part 46), investigators must obtain legally effective informed consent from research participants or their legally authorized representatives unless the research qualifies for exemption, the IRB approves a waiver of consent, or a limited emergency research waiver applies. Informed consent is a fundamental protection in human subjects research based on the ethical principle of respect for persons outlined in the Belmont Report. This principle requires that individuals be treated as autonomous agents and allowed to make voluntary, informed decisions about participation.

Types of Consent Informed Consent

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.

Assent Consent

Assent Consent is an 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. When writing an informed consent document, consider the potential participant's perspective.

Guidelines for Writing Informed Consent Forms

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

1. Statement of purpose of the study.
2. A brief description of methodology and duration of participant involvement.
3. Statement of risks/benefits to the participants.
4. Statement of data confidentiality.
5. Statement regarding the right of the participant to withdraw from the study at any time without negative consequences.
6. An offer to answer any questions the participant may have.
7. Contact information of all Principal Investigators and the contact information for TCCD's IRB irb@tccd.edu.
8. Lines for signature of participants and/or parents or legal guardian except for questionnaire research, in which return of questionnaire gives implied consent.
9. Statement that participant is 18 years of age or older unless parent or legal guardian has given consent.

A finalized informed consent form is required to be uploaded and submitted with proposal submission.

Below is an Informed Consent and Assent Consent Form Template for Creating an Informed Consent Letter. Please submit the **finalized Informed Consent Form** that will be distributed to participants.

Title of Study

Principal Investigator - Name, Phone, Email

Purpose of Study - Briefly describe purpose

Study Procedures - The study will include the following procedures [list in order]. (identify any experimental steps; explain all information will be explained in clear, non-technical language, note the time required per session and overall study duration).

Risks- Describe any foreseeable risks along with steps taken to minimize them. Inform participants that they may refuse to answer questions or withdraw from the study at any time without penalty.

Benefits - List any expected benefits to participants, others, or general knowledge.

Confidentiality- Describe specific protections, such as use of participant codes and secure data storage. Data will only be shared when required by law (e.g., abuse or suicide risk).

Compensation - State whether participants will receive payment, course credit, or no compensation, and conditions for eligibility if they withdraw early.

Contact Information - Provide Institutional Review Board contact information.

Voluntary Participation - State that participation is voluntary and participants may withdraw at any time without consequence.

Consent
I have read and I understand the provided information and have had the opportunity to ask questions. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without cost. I understand that I will be given a copy of this consent form. I voluntarily agree to take part in this study.

Participant's signature ___________________________ Date_______________
Investigator's signature ___________________________ Date _______________

Location Site Permission Approval

"Site Permission" may refer to physical locations as well as virtual environments or other private resources. Approved and documented Location Site Permission is required if you plan to do any of the following:

- Recruit participants in a closed and/or moderated social media group or recruit from the private contact list of an organization, school, or business.
- Use the private resources of an organization, school, or business to recruit participants or collect data or use the private resources of a site governed by its own Institutional Review Board (IRB).

Below is a sample letter requesting location site approval, followed by a sample site permission approval letter. You may use these templates when preparing your request. Please note that content within [brackets] should be replaced with the appropriate information in the final document

Sample Email Requesting Permission to Conduct Research Email

Subject: Request to Conduct Research

Dear [Name of Contact]**,**

I am requesting permission to conduct research at [insert site name/location] as part of my study, [insert title of project (dissertation, Master's, doctoral thesis)]. I am seeking approval for the period of [insert start date] through [insert end date].

Brief Description of the Research Study:

- **Research Study Title:** [Insert Research Study Title]
- **Study Activities at This Site:** [Briefly describe the activities that will occur at the site, such as distributing surveys, conducting interviews, or accessing databases.]
- **Site Support Needed:** [Describe any support required from the site, such as providing space, distributing materials, or facilitating participant contact.]

I have attached my IRB approval letter from [name of your degree-granting institution] for your reference. TCCD IRB will not review my proposal until I have TCCD site location approval. Please indicate your approval by signing the attached Location Site Approval Letter.

A sample location site approval letter is provided on the next page.
Should you need additional information or have any questions, please feel free to contact me. Thank you for your time and consideration.

Sincerely, [Your Name]

[Your Title/Position, if applicable]
[Your Institution or Affiliation]
[Your Contact Information]

Sample Site Permission Approval Letter

(to be completed by PI and the authorized representative of the site location.)
A location Site Approval Letter is required for each site. (e.g., if the study involves more than one TCC campus)

Date: [MM/DD/YYYY]

[Site Representative Name]
[Name of Site or Organization] [Address]

To Whom It May Concern:

This letter confirms that I, as an authorized representative of [Name of Site/Organization], grant permission to [Name of Principal Investigator] to conduct study-related activities at the location(s) listed below. These activities may begin once the Principal Investigator provides documentation of Tarrant County College District (TCCD) Institutional Review Board (IRB) approval for the proposed project.

Project Information:

- **Research Study Title**: [Insert Research Study Title]
- **Study Activities at This Site**: [Briefly describe the activities to be conducted at the site (e.g., surveys, interviews, interventions, or database access.)]
- **Site Support Provided**: [Describe the support the site will provide (e.g., space for data collection, permission to distribute materials, etc.)]
- **Other Arrangements**: [If applicable, outline any additional agreements or requirements related to the research.]
- **Anticipated End Date**: [Insert the anticipated end date of the research at this site.]

I understand that all research activities must comply with applicable regulations, including the Health Insurance Portability and Accountability Act (HIPAA), the Family Educational Rights and Privacy Act (FERPA), and any other site-specific policies. These requirements must be addressed prior to the researcher collecting or receiving data from the site.

We acknowledge that TCCD's participation in this research will occur only during the period of active IRB approval. All study-related activities must cease immediately if IRB approval expires, is suspended, or withdrawn.

If we have any concerns related to this project, we will contact [Name of Principal Investigator], Principal Investigator, for project-specific information. For questions regarding IRB policies or human subject protections, we may contact the TCCD IRB at irb@tccd.edu.

Authorized Site Representative	Principal Investigator
Name:________________________________	Name: ________________________________
Title: ________________________________	Title: _________________________________
Signature: _____________________________	Signature:______________________________
Date: _________________________________	Date:__________________________________

Adverse Event Report

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).

Key requirements include:

- Prompt Reporting: Institutions must have written procedures to ensure timely reporting of unanticipated problems involving risk to the IRB, institutional officials, and the appropriate federal department or agency (45 CFR 46.103(a) & (b)(5)).
- IRB Review Requirements (45 CFR 46.111):
  - Risks to subjects must be minimized and reasonable in relation to anticipated benefits.
  - Research must include data monitoring to ensure subject safety when appropriate.
- IRB Authority (45 CFR 46.109 & 46.113):
  - IRBs must conduct annual continuing reviews and may observe the research or consent process.
  - IRBs can suspend or terminate approval if the study poses unexpected serious harm.
  - Unanticipated Problems involve incidents that are:
    - Unexpected in nature, severity, or frequency.
    - Related or possibly related to the research.
    - Suggest increased risk to participants or others.

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.

An Adverse Event Report Form is required to be uploaded and submitted with proposal submission form.

Ethnographic Research/Fieldwork

Ethnographic research, also known as fieldwork, involves observation of and interaction with the persons or groups being studied in the group's own environment. Fieldwork research proposals often do not fit a traditional research design or Institutional Review Board (IRB) review model. However, the same principles for protection of human subjects apply to these studies.

An Ethnographic Research/Fieldwork form is required to be completed (found on submission form.)

Offsite Locations - Research Performed at Non-TCCD Sites and Locations

IRB offsite locations refer to the places outside a primary institution's owned or operated facilities where human subjects research is conducted, requiring review by the institution's Institutional Review Board (IRB) to ensure participant rights and welfare are protected. These locations can be non- affiliated institutions, public spaces, or even homes, and the research conducted there may fall under the primary institution's oversight or require coordination with the offsite location's own IRB.

An Offsite Locations form is required to be completed (found on submission form.)

Other IRB Authorization Agreement

An Other IRB Authorization Agreement (IAA), a formal written agreement between two or more institutions engaged in human subjects research, form is required. This means that instead of multiple IRBs reviewing the same research, one IRB acts as the IRB of Record, streamlining the review process and reducing administrative burden.

Key points about other IRB Authorization:

- **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.

IRB Authorization Agreement is required to be uploaded and submitted with proposal submission form. (template can be found at IRB Authorization Agreement (IAA),)

Vulnerable Populations

Vulnerable Populations Minors (Children under the age of 18)

Children are considered a vulnerable population due to their limited ability to advocate for themselves, their inherent dependency on adults for care and decision-making, their limited intellectual and emotional capacities to provide informed consent, and their susceptibility to physical and psychological harm from abuse, exploitation, and environmental factors. This vulnerability is compounded by social, economic, and health disparities that can leave children at a higher risk of poor health outcomes and reduced well-being.

Vulnerable Populations Minors (Children under the age of 18) Categories:

- **CATEGORY 1 (§46.404)** - This proposed research poses no greater than minimal risk to children if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians. (Note: for research that qualifies for Expedited level of review).
- **CATEGORY 2 (§46.405)** - This proposed research poses greater than minimal risk to children and includes an intervention or procedure that **DOES hold out the prospect of a direct benefit** for the individual child **or** a monitoring procedure that is likely to contribute to the child's well-being.
- **CATEGORY 3 (§46.406) -** This proposed research poses greater than minimal risk to children and is presented by an intervention or procedure that **DOES NOT hold out the prospect of direct benefit** for the individual subject **or** by a monitoring procedure which is not likely to contribute to the well-being of the subject but is likely to yield generalizable knowledge about the subject's disorder or condition.
- **CATEGORY 4 (§46.407) -** This proposed research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. The Secretary of HHS will review and after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) there will follow opportunity for public review and comment.

Vulnerable Populations: Pregnant Women, Human Fetuses or Neonates

Pregnant women, fetuses, and neonates are considered vulnerable populations in research due to the potential for increased susceptibility to harm and the inability to provide informed consent, requiring additional protections under federal regulations, specifically 45 CFR Part 46 Subpart B. These regulations mandate preclinical studies, ensure minimal risk or direct benefit to the fetus, and require specific consent procedures to safeguard the woman and her developing child.

- § 46.204 - Research Involving Pregnant Women or Fetuses
- § 46.205(a)&(b) Research Involving Neonates of Uncertain Viability
- § 46.205(c) Research Involving Nonviable Neonates
- § 46.205(d) Research Involving Viable Neonates

Vulnerable Populations: Prisoners

Please read 45 CFR 46, Subpart C of the Department of Health and Human Services' website regarding the involvement of prisoners in research studies. "Prisoner" is defined as any individual involuntarily confined or detained in a penal institution. The term "prisoner" is intended to encompass individuals: (a) sentenced to an institution under a criminal or civil statute; (b) detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution or (c) detained pending arraignment, trial, or sentencing.

Research involving Prisoners:

- Is the study of the potential causes, effects, and processes of incarceration and of criminal behavior.
- Is a study of prisons as institutional structures or of prisoners as incarcerated persons.
- Represents research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults).
- Represents research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.
- It is epidemiologic research to describe the prevalence or incidence of a disease by identifying all cases or to study potential risk factor associations for a disease, where prisoners are not a particular focus of the research.

Note: Individuals on probation or parole are not considered to be incarcerated.

Other Vulnerable Populations

In addition to federally defined vulnerable populations, the IRB may identify other groups requiring added protection. Vulnerability may vary by institution and study. Populations needing special consideration include:

- Acutely Ill Individuals – Patients with urgent medical needs (e.g., in the Emergency Department) often lack time or capacity for informed consent, creating vulnerability.
- Decisionally Impaired Individuals – Capacity must be assessed before and during research participation. Consent may be obtained from a legally authorized representative or surrogate, under IRB approval and applicable regulations (see IRB Policy 8012.07).
- Economically Disadvantaged Persons – Vulnerable to undue influence due to financial incentives or access to otherwise unaffordable care.
- Educationally Disadvantaged Persons – Limited literacy or comprehension may prevent fully informed decisions.
- Elderly/Aged Persons – Cognitive decline, whether constant or fluctuating, may impair consent capacity and increase sensitivity to study risks.
- Incapacitated Persons – Illness, injury, unconsciousness, medication, substance use, degenerative disease, or severe disability may render individuals unable to consent.
- Individuals with Handicaps – Physical impairments (e.g., vision or hearing loss) may hinder understanding of research and consent documents.
- Minorities – Cultural or language barriers can affect comprehension and decision-making.
- Students and Employees – May face coercion or pressure due to their institutional role or relationship with investigators.
- Terminally Ill Patients – Require protection against coercion or undue influence but should not be excluded from research that may benefit them or to which they wish to contribute.

A Vulnerable Populations (Children, Pregnant Women, Human Fetuses/Neonates, or Prisoners) form is required to be completed. (found on submission form.)

Research Closure Form

An Institutional Review Board (IRB) research closure form, also known as a final report, is a document submitted by a principal investigator (PI) to notify the IRB that a human subjects research study has been concluded. This is required for studies to end IRB oversight.

This form should be completed when:

- All aspects of the research proposal have been concluded. This means data collection has ceased, participants are no longer being enrolled, no follow-ups with participants are planned, data is no longer being coded or analyzed.
- The study was never initiated, and there are no plans to begin it.
- The PI is leaving the institution without a plan to transfer the study to a new local PI.

A Research Closure Form is required to be completed within 30 days of your proposal end date. (found on TCC IRB Resources Page)

TCCD IRB Proposal Form

Submission of this form affirms that you have thoroughly reviewed the research study proposal guidelines and that you agree to comply with all applicable institutional policies and procedures. For a complete description of the TCCD IRB's purpose, authority, and operational procedures for safeguarding the rights and welfare of human research participants, please refer to the **TCCD IRB Charter.**

Access the **TCCD IRB Research Proposal Submission Form** using the link below. To facilitate timely completion of this form, applicants are strongly encouraged to review the entire submission form prior to initiation to ensure that all required information and supporting documents are prepared, completed, and readily available prior to beginning the submission process. This submission form will prompt applicants to upload the following required supporting documents.

1. Final approved research proposal.
2. Signed IRB approval from the degree-granting institution.
3. Signed Site Location Approval letter.
4. Human Research Protection (HRS) Training documentation for all investigators.
5. Final informed consent form for participants.
6. Final recruitment materials (e.g., flyers, emails).
7. Data collection instruments (e.g., surveys, questionnaires, interview guides).
8. Additional required forms, if applicable regarding: Ethnographic Fieldwork, Off-Site Location, Other IRB Authorization Agreement, Vulnerable Populations (Minors; Pregnant Women, Fetuses, and Neonates; Prisoners).

Incomplete submissions or missing documentation may delay review and processing by the Institutional Review Board.

Once the IRB receives all of the required documents, the board will begin the review. The IRB makes every effort to review proposals within **four weeks** of their receipt. Proposals submitted during the summer or during TCCD holidays may be delayed.

Actions of the IRB

The IRB will notify you via email (irb@tccd.edu) the decision regarding your proposal.
The IRB may take one of the following four actions regarding the proposed protocol:

- Approved
- Approved Subject to Restrictions
- Deferred
- Disapproved

Since a proposal may not be approved as submitted, you should allow sufficient time for the committee to re-review your proposal.

Click to open TCCD IRB Research Proposal Submission Form