IRB Research Proposal Submission Form

Research Proposal Title: _____

Principal Investigator: _____

Campus(es): _____ **Department**: _____

Phone: _____ **Email**: _____

Co-Investigator: _____

Campus(es): _____ **Department**: _____

Phone: _____ **Email**: _____

I. Expected Start Date and Completion Date: (You are not authorized to start any research on human subjects including subject recruitment until the IRB has approved the research protocol.)

Proposed Projected Starting Date: _____ **Proposed Projected Ending Date:** _____

II. Degree-granting Institution Name: _____

☐ Signed IRB proposal approval documentation from your degree-granting institution provided.

III. Human Subjects Testing Training:

In accordance with federal regulations, it is necessary for all individuals planning to submit a research project involving human subjects through the TCCD IRB to complete educational training on the protection of human research subjects prior to any IRB submissions for approval.

Principal Investigator:

Name of Training: _____ Certificate Expiration Date: _____

Co-Investigator (if applicable)

Name of Training: _____ Certificate Expiration Date: _____

☐ Certificates provided.

IV. Research Location:

☐ **NW** ☐ **NE** ☐ **S** ☐ **SE** ☐ **TR** ☐ **CN** ☐ **Off Site** ☐ **Other** _____

☐ Signed location site approval documentation provided.

V. Personnel Qualifications: List all research team members in the table below, including their role, relevant qualifications, training, and experience for the study procedures or population.

Name	Role in the study	Relevant qualifications, special training, and experience	Email
	Principal Investigator		
	Co-Investigator (if applicable)		
	Research Sponsor (if applicable)		
	Faculty Advisor (if applicable)		

VI. Funding: Indicate existing, potential, or pending sources of funding.

☐ **Federal** ☐ **State** ☐ **TCCD** ☐ **Personal Funds** ☐ **Other:** _____ ☐ **None (*No funding*)**

If federal monies will be used in connection with the proposed project, provide name of funding source, grant award number, and a copy of the grant proposal.

☐ Grant Proposal Provided.

VII. Research Classification:

A. Indicate if this study is categorized as **Minimal Risk (MR)** or **Greater than Minimal Risk (GMR)**.

☐ **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."

B. Indicate Exempt/Expedited Category:

Exempt Research Category (check one): 1☐ 2☐ 3☐ 4☐ 5☐ 6☐

Expedited Research Category (check one): 1☐ 2☐ 3☐ 4☐ 5☐ 6☐ 7☐ 8☐ 9☐

VII. Principal Investigator Research Proposal

Provide a copy of your proposal covering the following components: an introduction; statement of the problem; purpose and significance of the study; hypothesis; methodology; research questions; scope; conceptual or theoretical framework; assumptions, delimitations, and limitations; definitions of key terms; and a summary. Please indicate what page the below information can be found in your proposal.

	Proposal Contents	Page #
A.	**A review of the relevant literature.**	
B.	**Research Question or Hypothesis**: List the primary research questions, hypotheses, and / or objectives guiding this study.	
C.	**Research Study:** experimental or research design which will answer the research question hypothesis. Provide a step-by-step description of study procedures, including what data will be collected, when, where, and how. List all research locations (attach site permission letters as needed).	
D.	**Explanation of the method used for determining the sample size.** Provide the number of subjects (not a range), you intend to enroll over the course of the study**.**	
E.	**Explanation of how the data will be used** to answer the research question or hypothesis**.**	
F.	**Research Benefits:** List of any direct benefits to be gained from the research and/or to participants from their involvement in the study**.**	
G.	**Anticipated Risks:** A statement of anticipated risks to the physical and mental health, comfort and privacy of experimental subjects.	
H.	**Strategies to Minimize Risks:** Statement describing the measures that will be implemented to reduce or mitigate potential risks.	
I.	**Privacy/Confidentiality:** A description of the measures that will be taken to minimize risks and to ensure confidentiality of sensitive personal data during and after the research**.**	
J.	**Data Security:** Data Security for each phase of data's life cycle, including collection, transmission, accessing, collaboration, storage, analysis, reporting, and disposition. Who will be responsible for storage and disposition? **Record Retention Period:** 3 years after the closure of the protocol.	
K.	**Explicit information about the recruiting, selection and compensation of subjects.** **Recruitment:** Explain how participants will be identified and contacted, who provides access to contact information, and include permission letters/emails if needed. List all recruitment sources. **Materials:** Provide exact wording of recruitment materials (letters, emails, flyers, phone scripts, social media posts, etc.) and attach copies. **Compensation:** Describe compensation (e.g., cash, gift cards, course credit, raffle prizes), including type, timing, method of distribution, and confidentiality protections.	
L.	**Finalized versions of the following documents as applicable to your study:** Surveys / Questionnaires / Psychological & educational tests, Demographics surveys, Focus group instructions/questions, Observation data collection sheets, Educational materials**.**	
M.	**Informed Consent & Assent**: Describe the informed consent process, including when, where, and how subjects will be consented. Provide finalized copy of consent form to be signed by each subject before participation**.**	
N.	**Funding:** A statement of whether federal monies will be used in connection with the proposed project. Indicate existing, potential, or pending sources of funding **Costs:** List any participant costs or expenses associated with study participation.	
O.	**Population(s):** Describe the target population(s) of the study, for example: TCCD students, competent or healthy adults, vulnerable populations: children (Under 18), prisoners (Individuals involuntarily detained), pregnant women*. **Inclusion Criteria:** List all criteria for including subjects and explain the methods you will use to determine whether a subject is eligible based on your criteria. **Exclusion Criteria:** Explain any specific factors or contraindications that would make a subject ineligible to participate in this study. * If participants are or may become pregnant, describe potential risks to the fetus. Because a fetus cannot consent, special caution is required for research involving more than minimal risk.	
	Note: If vulnerable populations are used, additional paperwork is necessary. Attach appropriate form as required.	

VIII. Provide your informed consent documentation.

Informed consent serves as the ethical cornerstone of human subjects research. Participants must be given clear and sufficient information to fully understand the requirements of their involvement and the intended use of their data. Information about an individual cannot be obtained indirectly through another person (e.g., a family member) unless that individual has personally completed the informed consent process. Researchers should refer to the Office of Human Research Protections (OHRP) Informed Consent Checklist *(http://www.hhs.gov/ohrp/policy/consentckls.html).*

Informed Consent Checklist.

YES	NO	Informed Consent Components
☐	☐	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.
☐	☐	Is the consent form written in lay language?
YES	**NO**	**Does the consent form include each of the following elements?**
☐	☐	Is it free of any language that requires the subjects to waive their legal rights, including any release of the investigator, sponsor or District or its agents from liability for negligence?
☐	☐	If minors are included in the study, is provision made for obtaining parental consent?
☐	☐	a. A statement that the study involves research and an explanation of the purposes of the research and the expected duration of the subject's participation.
☐	☐	b. A description of the procedures to be followed.
☐	☐	c. A description of any benefits to the subject or others.
☐	☐	d. A description of any reasonably foreseeable risks or discomforts.
☐	☐	e. A statement describing the extent to which confidentiality of records identifying the participant will be maintained.
☐	☐	f. Information regarding whom to contact for answers to questions about the research study and the research subject's rights.
☐	☐	g. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits and the participant may discontinue participation at any time without penalty or loss of benefits.
If there was **NO** response to any of the above questions, the consent form must be revised accordingly unless the investigator can satisfactorily justify why it is appropriate as submitted.		

IX. Conflict of Interest Acknowledgement - Does the principal investigator or any research personnel (internal and external) have an affiliation, arrangement, or financial interest that could be perceived as a conflict of interest?

Principal Investigator		Co-Investigator	
☐	No, I do not have a conflict of interest on this proposal.	☐	No, I do not have a conflict of interest on this proposal.
☐	Yes, I do have a conflict of interest on this proposal.	☐	Yes, I do have a conflict of interest on this proposal.
Faculty Advisor		**Research Sponsor**	
☐	No, I do not have a conflict of interest on this proposal.	☐	No, I do not have a conflict of interest on this proposal.
☐	Yes, I do have a conflict of interest on this proposal.	☐	Yes, I do have a conflict of interest on this proposal.

If yes, fully explain and identify the safeguards taken to prevent investigator bias in subject recruitment and/or the consent process. Investigators must comply with **TCCD's Board Policy Manual, Section DBD**, Employment Requirements and Restrictions, Conflict of Interest Policy.

X. Research Misconduct Guidelines.

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, **research misconduct** means fabrication, falsification or plagiarism in proposing, performing or reviewing research, or in reporting research results: (a) **Fabrication** is making up data or results and recording or reporting them, (b) **Falsification** is manipulating research materials, equipment or processes, or changing or omitting data or results such that the research is not accurately represented in the research record and (c) **Plagiarism** is the appropriation of another person's ideas, processes, results or words without giving appropriate credit. You can find more information about misconduct polices and processes in the Investigation of Allegations of Research Misconduct section of the NIH Sourcebook. The NIH Sourcebook also offers Responsible Conduct of Research Training

I certify that I have reviewed the Research Misconduct Guidelines and affirm my commitment to comply with all applicable policies and procedures.

Signature of Principal Investigator: _____ **Date:** _____

Signature of Co-Investigator: _____ **Date:** _____

XI. Responsibilities and Assurance of the Principal Investigator.

I understand that approval of this human subject research is contingent upon my agreement to do the following:

As **Principal Investigator**, I acknowledge that I am responsible for:

a. Securing IRB approval before initiating any research involving human subjects.
b. Ensuring that all study personnel have completed the mandatory research compliance training,
c. Ensuring the rights and welfare of human subjects through the ethical conduct of research, consistent with federal regulations and TCCD policies.
d. Obtaining IRB approval of modifications **prior** to the implementation of any changes from the approved version. This includes, but is not limited to, changes in: (a) title, (b) investigators, (c) funding source, (d) data collection methods, (e) recruitment materials, (f) confidentiality measures or (g) test instruments.
Please 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.
e. Reporting any unanticipated, adverse research events to the IRB within the specified time frame. Serious unanticipated events such as death or severe injury of a research participant are to be reported to the IRB within 24 hours of becoming aware of the event. Non-serious unanticipated events are to be reported within two weeks of the Principal Investigator's awareness of the non- serious, unanticipated event.
Unanticipated problems involving risks to subjects or others that are:
    i. Unexpected in nature, severity, or frequency.
    ii. Related or possibly related to the research.
    iii. Suggest increased risk to participants or others.
    iv. Serious or continuing noncompliance with the federal regulations or the requirements or determinations of the IRB.
f. Obtaining informed consent and data from human subjects in a manner consistent with federal regulations, maintaining copies of pertinent research documents and the confidentiality of human subject data, and retaining informed consent documents for a period of three years after the project.
g. Arranging for a co-Principal Investigator in the event I will be out of the office for vacation or illness.
h. Notifying the TCCD IRB chairperson when the research proposal has been approved or modified by another institution's IRB.
i. Providing a copy of the **final research results** to TCCD's IRB and complete the IRB's **Research Closure Form.**
j. Unless otherwise directed by the IRB Chairperson, I will renew this application with the IRB no less than annually.

I certify that the research project will be conducted in compliance with the IRB's understanding and recommendations. The IRB will be provided with all the information on the research project necessary for its complete review. I certify that this research project will not start until the final IRB approval is received.

Signature of Principal Investigator: _____ **Date:** _____

Signature of Co-Investigator: _____ **Date:** _____

Signature of Research Sponsor: _____ **Date:** _____
(If different from Principal Investigator)

XII. Research Proposal Submission Instructions:

New Proposal Submission: Email TCCD IRB **irb@tccd.edu** the below documents.

1. **Completed** IRB Research Proposal Form (this form)
2. **Signed** finalized IRB research study approval document from your degree granting institution.
3. **Approved** finalized copy of your research proposal (for example chapter 1 of your dissertation with an introduction, statement of the problem, the purpose/significance of the study, hypothesis, methodology, research questions, scope, conceptual/theoretical framework, assumptions-delimitations-limitations, definition of terms used and summary).
4. **Signed** Site Location approval letter.
5. **Completion** of HRS Training Certification/Documentation. (of all investigators in the study)
6. Informed Consent Document
7. Any Recruiting Materials (Flyers, emails, etc.)
8. Data Instruments (survey(s), questionnaire(s), interview guides(s)
9. 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 – Children
   - Vulnerable Populations – Pregnant Women, Fetuses and Neonates
   - Vulnerable Populations – Prisoners