Tarrant County Community College
Institutional Review Board
Full Committee Reviewer's Checklist

IRB# : **Researcher:**

Title: **Reviewer:**

HUMAN RESEARCH PROTECTIONS - ADMINISTRATIVE CHECKLIST

Required Signatures Provided	YES ☐	NO ☐		
Consent Document(s) Provided	YES ☐	NO ☐	N/A ☐	
Recruitment Material Included	YES ☐	NO ☐	N/A ☐	
Data Collection Instrument Included	YES ☐	NO ☐	N/A ☐	
Protocol Provided	YES ☐	NO ☐	N/A ☐	
Special Populations Identified	YES ☐	NO ☐	N/A ☐	If yes, Vulnerable Populations form(s) required
Source of Funding Identified	YES ☐	NO ☐		
Human Subjects section of Federal Grant Application/Proposal Provided	YES ☐	NO ☐	N/A ☐	If federally funded, a copy of the "Human Subjects" section of funding proposal is required
Permission Letters	YES ☐	NO ☐	N/A ☐	If research is conducted at non-TCCD site, additional paperwork is required

ADMINISTRATIVE COMMENTS

ADMINISTRATIVE QUESTIONS/NOTES (Questions and notes directed to the committee.)

MAJOR CONCERNS (Ethical concerns, risk/benefit issues, subject capacity, consent issues, privacy and confidentiality issues.)

MINOR ISSUES (Typographical errors, grammar, pagination, and/or required UCI template language missing from consent.)

REVIEWERS:

A. Please review the federal criteria for IRB approval and indicate whether the research meets each criterion by checking the appropriate box. List any concern that you would like communicated to the researcher in the corresponding comment box.

CRITERIA FOR IRB REVIEW AND APPROVAL			
			COMMENTS or JUSTIFICATION *(required)*
1	The IRB has the expertise needed to review this research.	☐ YES ☐ NO	
2	I, the IRB reviewer, have a conflict of interest on this protocol.	☐ YES ☐ NO	
3	The statement of purpose/hypothesis is adequate.	☐ YES ☐ NO	
4	Study personnel appear appropriate and qualified.	☐ YES ☐ NO	
5	The study procedures in the narrative match the consent document(s).	☐ YES ☐ NO ☐ N/A	
6	The risks described in the narrative adequately cover all of the study risks.	☐ YES ☐ NO	
7	The risks described in the narrative are consistent with the consent document.	☐ YES ☐ NO ☐ N/A	
Risk*/Benefit Assessment			
8	Risks to subjects will be minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to	☐ YES ☐ NO	

	risk.		
9	Risks to subjects will be minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.	☐ YES ☐ NO ☐ N/A	
10	Risks to subjects are reasonable in relation to both: • anticipated benefits, if any, to subjects; and • the importance of the knowledge that may reasonably be expected to result.	☐ YES ☐ NO	
Subject Selection			
11	Selection of subjects is equitable in relation to the purposes of the research and the setting in which the research will be conducted.	☐ YES ☐ NO	
12	Selection of subjects is appropriate (i.e., inclusion/exclusion criteria) based on the research and the setting in which the research will be conducted.	☐ YES ☐ NO	
13	The recruitment process will minimize the potential for undue influence or coercion.	☐ YES ☐ NO	
14	Compensation - neither the amount of payment nor the proposed method and timing of disbursement is coercive or presents potential for undue influence.	☐ YES ☐ NO	
15	Recruitment materials are appropriate	☐ YES ☐ NO ☐ N/A	
Subject Protections			
16	The research plan makes adequate provisions to protect the privacy of subjects.	☐ YES ☐ NO	
17	The research plan makes adequate provisions to maintain the confidentiality of data.	☐ YES ☐ NO	
18	The research **does** involve subjects likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons or economically or educationally	☐ YES ☐ N/A	If Vulnerable Populations are involved, additional forms are required.

	disadvantaged persons. **If YES,** the research plan **does** include additional safeguards to protect their rights and welfare.	---------- ☐ YES ☐ NO ☐ N/A	

*** Risks** include possible physical, psychological, economic, social and legal harms.

B. Risk Assessment:

☐ Virtually no risk [Exempt Registration]+

If research qualifies as Exempt, *provide the category(ies)*: _

☐ No more than Minimal Risk [Expedited review] +

If research qualifies as Expedited *provide the category(ies)*:

☐ Greater than Minimal Risk [Full Committee review]

+Please provide a brief rationale for your risk assessment - Exempt or Expedited review

C. Informed Consent Process:

Please review and confirm the circumstances of the consent process. Next, confirm the presence of all applicable elements of informed consent in the consent document (e.g., consent form, information sheet, or verbal telephone script). List any concerns that you would like communicated to the researcher in the corresponding comment box or in the open space below.

Circumstances of Consent			
			REVIEWER COMMENTS
1	Informed consent will be documented by obtaining the appropriate signatures on the informed consent form.	☐ YES ☐ NO ☐ N/A	
2	The researcher will obtain legally effective informed consent of either the: ☐ Subject ☐ Subject's legally authorized representative.	☐ YES ☐ NO	
3	The circumstances of consent provide the prospective subject sufficient opportunity to consider whether or not to participate.	☐ YES ☐ NO	
4	The circumstances of consent minimize the possibility of coercion or undue influence.	☐ YES ☐ NO	
5	The information that will be given to the subject will be in a language understandable to the individual.	☐ YES ☐ NO	
6	No information will be provided to the subject that waives or appears to waive any of the subject's	☐ YES ☐ NO	

	legal rights.		
7	No information will be provided to the subject that releases or appears to release the researcher, the sponsor, the institution or its agents from liability for negligence.	☐ YES ☐ NO	
8	The subject or the subject's surrogate decision maker will sign and date the informed consent form.	☐ YES ☐ NO ☐ N/A	
9	A copy of the informed consent document will be given to the person signing the form.	☐ YES ☐ NO ☐ N/A	
	THE CONSENT DOCUMENT/PROCESS WILL…		**COMMENTS**
1	Explain the purpose of the research.	☐ YES ☐ NO	
2	Disclose that the study involves research.	☐ YES ☐ NO	
3	Explain the expected duration of the subject's participation.	☐ YES ☐ NO	
4	Describe the procedures to be followed.	☐ YES ☐ NO	
5	Identify any procedures that are experimental.	☐ YES ☐ NO ☐ N/A	
6	Describe any reasonably foreseeable risks or discomforts to the subject.	☐ YES ☐ NO	
7	Describe any benefits to the subject or to others which may reasonably be expected from the research.	☐ YES ☐ NO	
8	Disclose appropriate alternative procedures or courses of treatment, if any that might benefit the subject.	☐ YES ☐ NO ☐ N/A	
9	Disclose the extent, if any, to which confidentiality of records identifying the subject will be maintained.	☐ YES ☐ NO	
10	Includes a statement explaining whom to contact for answers to pertinent questions about the research and about the research subjects' rights.	☐ YES ☐ NO	
11	Explain whom to contact in the event of a research-related injury to the subject.	☐ YES ☐ NO	
12	Disclose that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and that the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.	☐ YES ☐ NO	

Additional Elements of Informed Consent, as appropriate			
	THE CONSENT PROCESS WILL…		**COMMENTS**
13	***Choose one of the following:*** ☐ The approximate number of subjects involved in the study is not important in making a decision to participate in research. ☐ Explain the approximate number of subjects involved in the study (# at TCCD / total # for all study sites).	☐ YES ☐ NO	
14	***Choose one of the following:*** ☐ The risk profile of all research-related interventions is well known and the research involves no investigational drugs or devices. ☐ Disclose that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.	☐ YES ☐ NO	
15	***Choose one of the following:*** ☐ The research excludes women of child bearing potential and pregnant women. ☐ The risk profile of all research interventions or interactions on embryos and fetuses is well known. ☐ Disclose that the particular treatment or procedure may involve risks to the embryo or fetus, if the subject is or may become pregnant, which are currently unforeseeable.	☐ YES ☐ NO	
16	***Choose one of the following:*** ☐ There are no costs to the subject that may result from participation in the research. ☐ Disclose additional costs to the subject that may result from participation in the research. **AND** ☐ Disclose study compensation.	☐ YES ☐ NO --- ☐ YES ☐ NO	
17	***Choose one of the following:*** ☐ There are no anticipated circumstances under which the subject's participation will be terminated by the researcher without regard to the subject's consent. ☐ Disclose anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.	☐ YES ☐ NO	

18	***Choose one of the following:*** ☐ There are no adverse consequences (physical, social, economic, legal or psychological) of a subject's decision to withdraw from the research. ☐ Disclose the following information: • The consequences of the subject's decisions to withdraw from the research. • The orderly termination of participation by the subject.	☐ YES ☐ NO	
19	***Choose one of the following:*** ☐ Significant new findings during the course of the research which may relate to the subject's willingness to continue participation are <u>unlikely</u>. ☐ Include a statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation will be provided to the subject.	☐ YES ☐ NO	
20	***Choose one of the following:*** ☐ The research involves no more than minimal risk and there is not even the appearance of a financial conflict of interest. ☐ Disclose that that no one on the study team has a disclosable financial interest in the outcome of this study. ☐ Disclose that a member of the study team personal financial interest in either the Sponsor or another interested entity. The nature of this financial interest and the design of the study have been reviewed by the Office of Grants Development and Compliance and they determined that the investigator's financial interests would not compromise the quality or reliability of the study.	☐ YES ☐ NO	

Informed Consent Requirements Are: ☐ Met ☐ Not Met

D. IRB Recommendation: ☐ Approve

☐ Minor Changes

☐ Tabled to full Committee

☐ Disapprove

E. IRB Review cycle: ☐ 12 mos. ☐ 6 mos.* ☐ 3 mos.* ☐ Other*:

* **Please provide a rationale below if recommended review cycle is less than 12 months.**

Additional Comments [optional]:

Reviewer's Signature:

Date:

Note: The information provided on this form may be preliminary and may not necessarily reflect the discussion and final decision and/or recommendation of the full IRB committee.