Expires:

Tarrant County College District
Institutional Review Board
Continuing Review Checklist

IRB# : **Researcher:**

Title: **Reviewer:**

HUMAN RESEARCH PROTECTIONS - ADMINISTRATIVE CHECKLIST

Required Signatures Provided	YES ☐	NO ☐		
Consent Document(s) Provided	YES ☐	NO ☐	N/A ☐	
Original Protocol Provided	YES ☐	NO ☐	N/A ☐	
Summary of Adverse Events Provided	YES ☐	NO ☐	N/A ☐	
Special Populations Identified	YES ☐	NO ☐	N/A ☐	*If yes, Vulnerable Population form necessary*
Source of Funding Identified	YES ☐	NO ☐		
Permission Letters	YES ☐	NO ☐	N/A ☐	*If research is conducted at non-TCCD site, additional forms are required*

IRB REVIEWERS: Please review the progress of the study and perform a risk-benefit assessment to determine whether continuing approval is warranted (i.e., Does the study still meet the criteria for IRB approval?). Although the IRB has broad latitude to request changes, the focus of the continuing review should be on the subject of safety, regulatory and policy issues and adequacy of the informed consent process/documentation.

PROTOCOL SUMMARY

IRB Approved Sample Size:	
Number of Subjects Enrolled Since Last IRB Review:	
Number of Subjects Enrolled To Date:	
Number of Subjects to be Enrolled During Next Approval Period:	

Study Summary –

To date, [# or No] Adverse Events Reports have been reported for this protocol.

During the current approval period, [# or No] Modification requests were submitted for this protocol. Please specify approved modifications.

ADMINISTRATIVE QUESTIONS/NOTES (Questions and notes to the committee not related to major issues.)

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

MINOR ISSUES (Typographical errors, grammar, and/or required informed consent language missing.)

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 conflicting interest with 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 protocol 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	
8	The protocol needs verification from	☐ YES ☐ NO	

	outside sources that no material changes have occurred since the previous IRB review.		*If yes, from whom?*
9	The researcher has provided sufficient information to warrant continuation of the study.	☐ YES ☐ NO	
Risk*/Benefit Assessment			
10	Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.	☐ YES ☐ NO	
11	Risks to subjects are minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.	☐ YES ☐ NO ☐ N/A	
12	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			
13	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	
14	Selection of subjects (i.e., inclusion/exclusion criteria) is appropriate based on the research and the setting in which the research will be conducted.	☐ YES ☐ NO	
15	The recruitment process minimizes the potential for undue influence or coercion.	☐ YES ☐ NO	
16	Compensation - neither the amount of payment nor the proposed method and timing of disbursement is coercive or presents potential for undue influence.	☐ YES ☐ NO	
17	Recruitment materials are appropriate.	☐ YES ☐ NO ☐ N/A	
Subject Protections			
18	The research plan makes adequate	☐ YES ☐ NO	

	provision for monitoring the data collected to ensure the safety of subjects.		
19	The research plan makes adequate provisions to protect the privacy of subjects.	☐ YES ☐ NO	
20	The research plan makes adequate provisions to maintain the confidentiality of data.	☐ YES ☐ NO	
21	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 disadvantaged persons. **If YES,** the research plan **does** include additional safeguards to protect their rights and welfare.	☐ YES ☐ N/A --- ☐ YES ☐ NO ☐ N/A	

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

A. Risk Assessment: ☐ No more than Minimal Risk [Expedited review]

If **<u>Minimal Risk</u>**, *indicate corresponding category(ies)*:

☐ Greater than Minimal Risk [Full Committee review]

Please provide a rationale for any change in the risk assessment (e.g., from Expedited to full Committee or vice versa).

CONSENT PROCESS CHECK LIST

B. 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 obtains the legally effective informed	☐ YES	

	consent of either the: ☐ Subject ☐ Subject's legally authorized representative	☐ 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 LAR will be in a language understandable to the subject or the representative.	☐ YES ☐ NO	
6	The information provided to the subject is still accurate and complete.	☐ YES ☐ NO	
7	No information will be provided to the subject or surrogate that waives or appears to waive any of the subject's legal rights.	☐ YES ☐ NO	
8	No information will be provided to the subject or surrogate that releases or appears to release the researcher, the sponsor, the institution or its agents from liability for negligence.	☐ YES ☐ NO	
9	Significant new findings related to the subjects' willingness to continue participation were/should be provided to the subjects in accordance with regulations.	☐ YES ☐ NO ☐ N/A	If yes, explain:
10	The subject or the subject's legally authorized representative sign and date the informed consent form.	☐ YES ☐ NO ☐ N/A	
11	A copy of the informed consent document is given to the person signing the form.	☐ YES ☐ NO ☐ N/A	

Basic Elements of Informed Consent			
	THE CONSENT PROCESS…		**COMMENTS**
1	Explains the purpose of the research.	☐ YES ☐ NO	
2	Discloses that the study involves research.	☐ YES ☐ NO	
3	Explains the expected duration of the subject's participation.	☐ YES ☐ NO	
4	Describes the procedures to be followed.	☐ YES ☐ NO	
5	Identifies any procedures that are experimental.	☐ YES ☐ NO ☐ N/A	
6	Describes any reasonably foreseeable risks or discomforts to the subject.	☐ YES ☐ NO	

7	Describes any benefits to the subject or to others which may reasonably be expected from the research.	☐ YES ☐ NO	
8	Discloses appropriate alternative procedures or courses of treatment, if any that might be advantageous to the subject.	☐ YES ☐ NO ☐ N/A	
9	Discloses 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	Explains whom to contact in the event of a research-related injury to the subject.	☐ YES ☐ NO	
12	Discloses 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	
13	***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	
14	***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. **<u>AND</u>** ☐ Disclose study compensation.	☐ YES ☐ NO ☐ YES ☐ NO	
15	***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.	☐ YES ☐ NO	

	☐ Disclose anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent.		
16	***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	
17	***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	
18	***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 significant 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 UCI Conflict of Interest Oversight Committee, and that this committee has 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

C. IRB Recommendation: Research may be restricted, modified, suspended or terminated altogether based on continuing review by the IRB Committee.

☐ Approved as is

☐ Minor Changes *[e.g., if specific restrictions are imposed]*

☐ Tabled to Subcommittee [Minimal Risk protocols *only*]

☐ Tabled to Full Committee *[greater than Minimal Risk protocols, if substantive clarifications required or restrictions are imposed]*

☐ Suspended ☐ Terminated

Please provide a rationale below if recommendation is to table, restrict, suspend or terminate the research.

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

* **Please provide a rationale below if recommended review frequency 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.