Tarrant County College District
Institutional Review Board
Expedited 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 Provided	**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 QUESTIONS AND NOTES (Questions/notes to IRB)

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

MINOR ISSUES (Typographical errors, grammar, pagination and/or 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 to communicate to the researcher in the corresponding comment box.

CRITERIA FOR IRB REVIEW AND APPROVAL			
			REVIEWER'S COMMENTS *[optional]*
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	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 are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.	☐ YES ☐ NO	
9	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	
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 purpose of the research	☐ YES ☐ NO	

	and the setting in which the research will be conducted.		
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 disadvantaged persons. **If YES,** the research plan **does** include additional safeguards to protect their rights and welfare and the appropriate *Vulnerable Populations* form was provided.	☐ YES ☐ N/A ---------- -- ☐ YES ☐ NO ☐ N/A	

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

B. **Risk Assessment:**

☐ Virtually no risk [Exempt Registration].
If Exempt*, please indicate corresponding category(ies)*:

☐ No more than Minimal Risk [Expedited review]

☐ Greater than Minimal Risk [Full Committee review]

[+]**Please provide a brief rationale for your risk assessment - Exempt status or full Committee review**

C. **Expedited Review Applicability**: Please confirm that the following are true by checking each box:

☐ The expedited review research procedures will not be used where the identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

☐ The expedited review research procedures will not be used for classified research (e.g., military classified) involving human subjects.

D. Categories of Research: If a project qualifies as Expedited, please check the appropriate category(ies).

		Expedited Categories
☐	**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 e*ither of the following are true*: o An investigational device exemption application (21 CFR Part 812) is not required; or o The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
☐	**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.
☐	**3**	• Research involving the prospective collection of biological specimens for research purposes by noninvasive means. Examples include: ▪ Hair and nail clippings in a nondisfiguring manner ▪ Deciduous teeth at time of exfoliation or if 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 gumbase 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.
☐	**4**	• Research involving the collection of data through noninvasive procedures routinely employed in clinical practice • Research **NOT** involving general anesthesia or sedation. • Research **NOT** involving 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.
☐	**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.
☐	**6**	• Research involving the collection of data for research purposes from one of the following: ▪ Voice recording ▪ Video recording ▪ Digital recording ▪ Image recordings.
☐	**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.
☐	**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
☐	**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.

E. Informed Consent Process:

Please review and confirm the conditions 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 the legally effective informed consent of the: ☐ Subject	☐ YES ☐ NO	

	☐ Subject's legally authorized representative		
3	The circumstances of consent provide the prospective subject or the representative 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 subject or the representative.	☐ YES ☐ NO	
6	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	
7	No information will be provided to the subject or surrogate that releases or appears to release the researcher, sponsor, institution or its agents from liability for negligence.	☐ YES ☐ NO	
8	The subject or the subject's legally authorized representative 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 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 be advantageous to 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	Include 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	☐ YES ☐ NO	

	subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.		
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.	☐ YES ☐ NO	

	☐ Disclose the following information: • The consequences of the subject's decisions to withdraw from the research. • The orderly termination of participation by the subject.		
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 unlikely. ☐ 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 significant financial interest in the outcome of this study.	☐ YES ☐ NO	

Informed Consent Requirements Are: ☐ Met ☐ Not Met

F. IRB Recommendation:

☐ Approve

☐ Minor Changes

☐ Tabled back to Subcommittee

☐ Tabled to Full Committee

G. 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.