Tarrant County College District
Institutional Review Board
Exempt Reviewer's Checklist

IRB# : **Researcher:**

Title: **Reviewer:**

HUMAN RESEARCH PROTECTIONS CHECKLIST

Required Signatures Provided	YES ☐	NO ☐		
Consent Document Provided	YES ☐	NO ☐	N/A ☐	
Recruitment Material Included	YES ☐	NO ☐	N/A ☐	
Data Collection Instrument Included	YES ☐	NO ☐	N/A ☐	
Special Populations Identified	YES ☐	NO ☐	N/A ☐	*If vulnerable populations are used, additional paperwork is required.*
Source of Funding Identified	YES ☐	NO ☐		
Use of student population in research defended, if applicable.	YES ☐	NO ☐	N/A ☐	
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 to the committee.)

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

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

REVIEWERS:

A. Please specify whether you have a conflict of interest with the review of this protocol.

☐ **I DO NOT HAVE A CONFLICT OF INTEREST ON THIS PROTOCOL**

☐ **I DO HAVE A CONFLICT OF INTEREST ON THIS PROTOCOL**

Please review and confirm that the research meets the outlined criteria below by checking the corresponding box. Please document **each** concern that you would like to be communicated to the researcher in the corresponding comments box or in the open space below.

<table>
<tr><th colspan="2">CRITERIA FOR EXEMPT REGISTRATION</th></tr>
<tr><th>BACKGROUND AND RESEARCH DESIGN</th><th>RISK/BENEFIT ANALYSIS</th></tr>
<tr><td>-Statement of purpose/hypothesis is adequate
-Study personnel appear appropriate/qualified</td><td>-Risks are relatively non-existent
-Potential direct benefit to subjects or societal benefit included
-Acceptable risk/benefit relationship</td></tr>
<tr><td>☐ YES ☐ NO</td><td>☐ YES ☐ NO</td></tr>
<tr><td>Comments:</td><td>Comments:</td></tr>
<tr><th>SUBJECT RECRUITMENT</th><th>SUBJECT PROTECTION</th></tr>
<tr><td>-Selection of subjects is appropriate
-Selection of subjects is equitable
-Recruitment procedures are proper (undue influence or coercion is minimized, compensation is not coercive, recruitment materials are appropriate)</td><td>-Unanticipated problem reporting is adequately addressed
-Provisions to protect subject privacy are adequate
-Provisions to maintain confidentiality are appropriate
-Additional protections for vulnerable populations are addressed</td></tr>
<tr><td>☐ YES ☐ NO ☐ N/A</td><td>☐ YES ☐ NO</td></tr>
<tr><td>Comments:</td><td>Comments:</td></tr>
<tr><th colspan="2">INFORMED CONSENT</th></tr>
<tr><td colspan="2">Is an informed consent process appropriate?</td></tr>
</table>

☐ **YES*** ☐ **NO, provide a rationale below** ☐ **N/A**	
***If yes,** the researcher will disclose: -That the activity involves research -A description of the procedures	-That participation is voluntary -There are adequate provisions to maintain privacy and confidentiality -The name and contact information for the researcher
☐ **YES** ☐ **NO**	
Comments:	

B. Risk Assessment: ☐ Virtually no risk [Exempt Registration]

☐ No more than Minimal Risk [Expedited review] ☐ Greater than Minimal Risk [Full Committee review]

Please provide a brief rationale for your risk assessment if the research requires Expedited or Full Committee review.

C. Categories of Research: If project qualifies for Exempt review, please check the appropriate category(ies).

Exempt Categories		
☐	**1**	• Research conducted in established or commonly accepted educational settings. • The research involves normal educational practices, such as (a) research on regular and special education instructional strategies or (b) research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods. ▪ **The research is not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.** • The research is **not** subject to FDA regulations. • The research does **not** involve prisoners as subjects.
☐	**2**	• The research involves the use of one or more of the following: ▪ Educational tests (cognitive, diagnostic, aptitude, achievement) ▪ Survey procedures ▪ Interview procedures ▪ Observation of public behavior • If the research involves children as subjects, the procedures are limited to: ▪ Educational tests (cognitive, diagnostic, aptitude, achievement) ▪ Observation of public behavior where the researchers will **not** participate in the activities being observed. • If at least one of the following criteria are met:: ▪ Information obtained is **not** recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects.

		▪ Any disclosure of the human subjects' responses outside the research could **not** reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation. ▪ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7). • The research is **not** subject to FDA regulations. • The research does **not** involve prisoners as subjects.
☐	**3**	• Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: ▪ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects. ▪ Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or ▪ The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly
☐	**4**	• Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens collection and at least one of the following criteria is met: ▪ If these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects ▪ Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects ▪ The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR 164.501 or for “public health activities and purposes” as described under 45 CFR 164.512(b) ▪ Or the research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501. • The research is **not** subject to FDA regulations. • The research does not involve prisoners as subjects.
	5	• Research and demonstration projects which are conducted by or subject to the approval of department or agency heads and which are designed to study, evaluate or otherwise examine: • Public benefit or service programs • Procedures for obtaining benefits or services under those program • Possible changes in or alternatives to those programs or procedures

		• Possible changes in methods or levels of payment for benefits or services under those programs.
	6	• The research involves a taste and food quality evaluation and consumer acceptance studies. *One of the following is true:* ▪ Wholesome foods without additives will be consumed. ▪ A food is consumed that contains a food ingredient and both of the following are true: ▪ The food ingredient is at or below the level to be safe and ▪ The food ingredient is for a use found to be safe. ▪ A food will be consumed that contains an agricultural chemical or environmental contaminant and one of the following is true: ▪ The agricultural chemical or environmental contaminant is at or below the level found to be safe by the FDA, ▪ The agricultural chemical or environmental contaminant is at or below the level found to be safe by the EPA or ▪ The agricultural chemical or environmental contaminant is at or below the level approved by the Food Safety and Inspection Service of the U.S. Department of Agriculture.
	7	• Storage or maintenance for secondary research for which broad consent is required. Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).
	8	• Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met: ▪ Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d); ▪ (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117; ▪ (iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

D. IRB Recommendation: ☐ Exempt Registration Confirmed ☐ Requires Expedited Review

☐ Revisions/Clarifications Required ☐ Requires Full Committee Review

Reviewer's Signature: **Date:**