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 ☐		
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.

CRITERIA FOR EXEMPT REGISTRATION	
BACKGROUND AND RESEARCH DESIGN	**RISK/BENEFIT ANALYSIS**
-Statement of purpose/hypothesis is adequate -Study personnel appear appropriate/qualified	-Risks are relatively non-existent -Potential direct benefit to subjects or societal benefit included -Acceptable risk/benefit relationship
☐ **YES** ☐ **NO**	☐ **YES** ☐ **NO**
Comments:	Comments:
SUBJECT RECRUITMENT	**SUBJECT PROTECTION**
-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)	-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
☐ **YES** ☐ **NO** ☐ **N/A**	☐ **YES** ☐ **NO**
Comments:	Comments:
INFORMED CONSENT	
Is an informed consent process appropriate?	

☐ 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** 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. • Both of the following are true: ▪ 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 research is **not** subject to FDA regulations. • The research does **not** involve prisoners as subjects.
☐	**3**	• The research is **not** exempt under Category 2 above. • 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 • *Either of the following is true:* ▪ The subjects are elected or appointed public officials or candidates for public office. ▪ Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. • The research is **not** subject to FDA regulations. • The research does **not** involve prisoners as subjects.
☐	**4**	• The research involves the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens (The reviewed materials currently exist and are **not** prospectively collected). • *At least one of the following is true:* ▪ The sources are publicly available and/or ▪ Information is recorded by the researcher in such a manner that *both of the following are true:* ✓ Subjects cannot be directly identified and ✓ Subjects cannot be identified through identifiers linked to them. NOTE: *The researcher should describe what information will be recorded and how it will be recorded.* • The research is **not** subject to FDA regulations. • The research does not involve prisoners as subjects.
☐	**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.

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

☐ Revisions/Clarifications Required ☐ Requires Full Committee Review

Reviewer's Signature: **Date:**