TCSPP Institutional Review Board (IRB) Cover Page

The items in this document are locked and cannot be deleted. This document allows you to format your responses as needed (e.g., indent, italicize, etc.). Use your cursor to navigate through each section. Each item will move depending on the length of your response. For example, the longer your project title the further down Item 3 will move.

Cover Page			
1. Principal Invest	tigator's Information:		
Name:	Phone:		
Email address:			
Dept.	Campus:		
Type of researcher:			
☐ Faculty ☐ Dissertation Student ☐ Thesis Student			
☐ Student, non-degree ☐ ExCEL/MAP Student			
2. Project Title:			
[Delete this sentence and place your response here.]			
3. For student researcher, provide your dissertation/thesis chair's or primary advisor's information			
Name:	Phone:		
Email address:			
Dept.	Campus:		
4. Type of Research – Select only one category			
\square Exempt - Complete the "Exempt Review Requested" section.			
\square Expedited -Complete the "Expedited Review Requested" section.			
☐ Full Board	I		

V. 9/30/2014 1 of 3

Exempt Review Requested

Review the Exempt categories and indicate the category that applies to your research.

[Delete this sentence and place your response here.]

Exempt Categories

Please indicate below the category that appropriately describes your study. Please note if your study does not fall into one of the categories below it may not be reviewed as exempt.

- 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- 2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- 3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:
 (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, 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.
- 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:
 - (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
- 6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

V. 9/30/2014 2 of 3

Expedited Review Requested

Federal regulations provide that certain types of research may be considered for review through an expedited process (45 CFR 46.110). Click here for additional information. A primary criterion for expedited review is that the research be of minimal risk. The Office of Human Research Protections (OHRP) defines minimal risk as risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than that ordinarily experienced in daily life or during the performance of routine physical or psychological examinations. In addition, the purpose of the research must fit within a series of categories as stipulated by DHHS regulations.

Please confirm statements A and B are true for your study and indicate the appropriate category under C.

 B. The identification of the subjects/and or their responses would not reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that the risk to privacy and breach of confidentiality are no greater than minimal. C. Review the Expedited categories and indicate the category that applies to your research 	A. The research	ooses no greater than minimal risk.
\square C. Review the Expedited categories and indicate the category that applies to your research	the subject at ris standing, emplo and appropriate	k of criminal or civil liability or be damaging to the subject's financial yability, insurability, reputation, or be stigmatizing, unless reasonable protections will be implemented so that the risk to privacy and breach
	C. Review the Ex	pedited categories and indicate the category that applies to your research.

[Delete this sentence and place your response here.]

Expedited Categories

- 1. Clinical studies of drugs and medical devices.
- 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture.
- 3. Prospective collection of biological specimens for research purposes by noninvasive means.
- 4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they 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).
- 5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
- 6. Collection of data from voice, video, digital, or image recordings made for research purposes.
- 7. 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) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

V. 9/30/2014 3 of 3