Huston-Tillotson University
Institutional Planning, Research and Assessment
Institutional Review Board

REQUEST FOR IRB EXEMPTION

INTRODUCTION

Consistent with ethical research practices, Huston-Tillotson University considers that all research activities involving humans as research participants must be reviewed and approved by an Institutional Review Board (IRB), unless the Office of Institutional Planning, Research and Assessment and/or the IRB Committee determines that the research falls into one or more of the categories of exemption established by the Code of Federal Regulations.

CATEGORIES OF RESEARCH ACTIVITIES EXEMPT FROM REVIEW BY THE INSTITUTIONAL REVIEW BOARD

The Code of Federal Regulations, Title 45 CFR Part 46, identifies several different categories of minimal risk research as being exempt from Federal Policy for the Protection of Human Research Subjects. These exemptions **DO NOT APPLY** when **deception** of human participants may be an element of the research; when the activity might expose the human participants to **discomfort** or **harassment** beyond levels encountered in daily life; or when individuals **involuntarily confined** or **detained** in penal institutions are participants of the activity.

Category #1
Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

a. Research on regular and special education instructional strategies.
b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category #2
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, ***unless***:

a. Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; **AND**
b. Any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

NOTE: The exemption under Category 2 **DOES NOT APPLY** to research involving survey or interview procedures or observation of public behavior when **individuals under the age of 18** are

participants of the activity **except** for research involving **observations** of public behavior when the investigator(s) do not participate in the activities being observed.

Category #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 Category 2, **IF**:

a. The human participants are elected or appointed public officials or candidates for public office, **OR**
b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter

Category #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 participants cannot be identified directly or through identifiers linked to the participants.

Category #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:

a. Public benefit or service programs;
b. Procedures for obtaining benefits or services under those programs;
c. Possible changes in or alternatives to those programs or procedures; **OR**
d. Possible changes in methods or levels of payment for benefits or services under those programs.

Category #6
Taste and food quality evaluation and consumer acceptance studies,

a. If wholesome foods without additives are consumed; **OR**
b. 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.

Important: Applications that do not meet the criteria for exempt review will be recommended for either an expedited review or for full review by a convened IRB committee. Please make selections carefully; if an exempt submission is determined by the IRB not to meet these criteria, you will be asked to withdraw the application and submit a new one.

The IRB does not actually approve an exempt study but instead makes a determination that the project meets at least one of the federal exempt categories criteria. Therefore, annual review is not required and no expiration date will be listed on your approval letter. It is also very important that you close-out your project when completed or if you leave the university. Faculty are responsible for oversight of student projects and should ensure exempt studies are completed and closed-out before the student leaves the university.

GUIDELINES

Only a faculty member may serve as a principal investigator for student research. Each investigator listed on the signature page of the exempt application will receive an e-mail notification that the project is incomplete/requires clarification, approved for exempt status, or disapproved. A detailed e-mail will be sent asking for clarifications or changes to incomplete applications. Please allow three weeks to receive a determination of exempt status.

Exempt research is generally short term in nature. It usually is performed "as written" (i.e., the investigators do not plan to make changes in the research design, selection of participants, informed consent process, or study instruments during the course of the research). Investigators conducting research determined to be exempt are responsible for ensuring that the welfare of human participants partaking in research activities is protected and that the methods used and information provided to gain participant consent are appropriate to the activity.
Investigators may not solicit subject participation or begin data collection until they have received written or electronic concurrence from Huston Tillotson University's IRB Committee that the research has been determined to be exempt or written approval from the appropriate IRB.

To ensure an effective review, a full description of the planned research (i.e., a research protocol or proposal) must be submitted with the Exempt Application. A research protocol/proposal provides the reader with background information of the problem under study, including the study rationale, a detailed plan for conducting the research involving human research participants, and a discussion of the potential importance of the research.

The application below is to be used by those requesting an exempt determination. A suggested research protocol/proposal is also provided. **For more information, please contact Jaya Soni, Director of Institutional Planning, Research and Assessment and IRB Committee Chair at (512) 505-3019 or electronically at jksoni@htu.edu**

APPLICATION FOR IRB EXEMPTION

Instructions: To complete the form, click the underlined areas and type or paste in your text; double-click checkboxes to check/uncheck. **Mail, email or deliver all materials to Jaya K. Soni, Director, Office of Institutional Planning, Research and Assessment at jksoni@htu.edu or to Anthony E. and Louise Viaer Alumni Hall Office 310**

IINDICATE THE TYPE OF REVIEW:

☐ **New** ☐ **Continuing Review** ☐ **Final Report**

IRB PROTOCOL#_____

1. PROJECT TITLE:

2. PRINCIPAL INVESTIGATOR (OR ADVISOR) – see Qualifications for Service as a PI

Name (Last, First, MI):	Degree(s):
University Academic Title:	College:
Department Name:	Campus Mailing Address:
HT ID Number:	E-mail:
Phone:	Emergency phone:
Ethical Research Training: ☐ CITI Training, Date of Completion: ☐ NIH Training, Date of Completion:	

3. List all individuals who will be involved with the research, their degree(s) and job title, and any additional qualifications. Include individuals who will be involved in the consent process. *Repeat the table below for each individual.*

Role:	☐Co-Principal Investigator -*OR*- ☐ Other:
Full Name:	
Department Name (Employer if not HT)	
Degree(s) / Job Title:	
Additional Qualifications pertinent to the study:	

Is this activity funded in any way? ☐Yes ☐No

If yes, attach 1 copy of completed application and complete (i)-(iv):

i. Grant or Contract Title: _____

ii. PI of Grant or Contract: _____

iii. Office of Sponsored Programs Proposal Number: _____

iv. Funding Source: _____

4. **Please review the six categories of exemption listed below and mark the category or categories that apply to your proposed research.** *[Note: Exemptions do not apply for prisoners, or for research that specifically targets persons who have cognitive impairments or persons who are economically or educationally disadvantaged (i.e., vulnerable populations).*

☐ 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. The research is not FDA regulated and does not involve prisoners as participants.

☐ 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. Attach questionnaire(s) and/or surveys. If the research involves children as participants, the procedures are limited to educational tests and observation of public behavior where the investigators do not participate in the activities being observed. The research is not FDA regulated and does not involve prisoners as participants.

☐ 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 category (2), 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. Attach to this application a copy of any questionnaire or survey to be used. The research is not FDA regulated and does not involve prisoners as participants.

☐ 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. **Note: to be eligible for this exemption, all data, documents, records of specimens must exist prior to IRB review and must have been collected for purposes other than the proposed research. To qualify for an exemption in this category, the proposed research must be strictly retrospective**.

☐ 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. The protocol will be conducted pursuant to specific federal statutory authority; has no statutory requirement for IRB review; does not involve significant physical invasions or intrusions upon the privacy interests of the participant; has authorization or concurrent by the funding agency; and does not involve prisoners as participants.

☐ 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. The research does not involve prisoners as participants.

If the proposed research **does not** meet any of the above categories, please complete a full IRB review application.

5. Is a copy of the research protocol attached or included alongside this application for IRB exemption? ☐Yes ☐No

If not, please include a copy of research protocol or proposal outline. Failure to do so may delay or prevent IRB review.

6. Expected completion date:

RESEARCHER ASSURANCES:
I certify that the proposed research described above, to the best of my knowledge, qualifies as an exempt study. I agree that any changes to the project will be submitted to the IRB for review prior to implementation. I realize that some changes may alter the exempt status of this project. The original signature of the PI is required before this application may be processed (scanned or faxed signatures are acceptable).

_____ _____

Principal Investigator's Printed Name Date Submitted

_____

Principal Investigator's Signature

Applicable for Continuing Review or Final Report Only

State both the positive and negative results received to date:

Since the last IRB review, have any of the following occurred?

1. Have participants experienced any harm (expected or unexpected)?
   ☐Yes ☐No
   If yes, attach Problem Summary Sheet, and briefly describe here the harms (serious and/or non-serious) experienced by participants: _____

2. Have there been any unanticipated problems involving risks to participants or others?
   ☐Yes ☐No
   If yes, attach Problem Report, and briefly describe here the unanticipated problems involving risks to participants or others: _____

3. Have you have any problems obtaining informed consent?
   ☐Yes ☐No ☐N/A
   If yes, briefly describe the problems here: _____

4. Have any participants or others complained about the research?
   ☐Yes ☐No
   If yes, briefly describe the number and nature of the complaints: _____

5. Have any participants withdrawn from the research?
   ☐Yes ☐No
   If yes, indicate the number of withdrawals and include the reason for each: _____

6. Have any obvious, study-related benefits occurred for participants?
   ☐Yes ☐No
   If yes, briefly describe the benefits here: _____

7. Have the risks or potential benefits of this research changed?
   ☐Yes ☐No
   If yes, briefly describe the changes here: _____

8. **Has there been any** published literature?
   ☐Yes ☐No
   If yes, attach a copy and summarize the published findings here: _____

Principal Investigator's Printed Name:_____ Date: _____

Principal Investigator's Signature:

_____