University of North Texas Health Science Center
Office for the Protection of Human Subjects (OPHS) / Institutional Review Board (IRB)

Request for Review of EXEMPT Category Research Project

IRB # _____

ALL research involving human subjects requires review and consideration by the UNTHSC Office for the Protection of Human Subjects (OPHS) and the Institutional Review Board (IRB). Some research projects may be "exempt" from Full Board Review and thus qualify as "Exempt Category" research. To determine if your research project is in this category, provide information using the following form. Note that proof or declaration of Human Subjects Research Training for all study personnel must accompany this form. Also, incomplete applications and supporting documentation will delay OPHS-IRB review and approval of this project. If it is determined that your research project is NOT Exempt category research, you will need to re-submit a full protocol and a completed Expedited IRB Application Form. Attach page if more space is needed for any of the below. Go to website for guidance on what is NOT Exempt.

PROJECT INFORMATION

Faculty Research ☐ **Student Research:** ☐ **Masters** ☐ **Doctoral**

Title of Research Activity:

Name of Principal Investigator (Faculty Member):

Contact Information- Telephone: *Email Address:*

Name of Student Investigator:

Contact Information- Telephone: *Email Address:*

Department/Program:

Name(s) of each Co-Investigator (Study Personnel):

Project Description: Briefly state the objective(s) and procedures associated with this project. *Recall that incomplete or unclear information will delay OPHS-IRB review and approval* (**attach page if needed**)*:*

Educational Practices and Strategies: Yes ☐ **No** ☐ (If Yes, please answer **all** questions below)

Will research involve normal educational practices such as (check appropriate box)?

☐ Regular instructional strategies including those commonly used in a classroom
☐ Special education instructional strategies such as the use of a device for performing skill sets or exercise
☐ Effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
☐ Other:
☐ The study does not involve research in educational practices and strategies

Will research be conducted in an established or commonly accepted educational setting (university or teaching hospital)?

Yes ☐ **No** ☐ **[If yes, please answer the question below]**

Where will it be conducted?

Is the educational activity itself part of your research or will the educational activity occur regardless of research?

☐ **Yes, it is part of research**
☐ **No, the practices are normal educational practices that will occur regardless of this research project**

Survey or Interview Study: Yes ☐ **No** ☐ (If Yes, please answer **all** questions AND attach copy of survey instruments and procedures)

Source of subject population:

Age Range of subjects to be included in the survey or interview:

Where will the survey/interview occur? (Location of activity):

Date(s) survey/interview to be conducted? (Include month and year) From _____ To _____

Will subjects be identified? **Yes** ☐ **No** ☐ Will subject responses be audio, video or digitally recorded? **Yes** ☐ **No** ☐

Will your subjects include children (under age 18)? **Yes** ☐ **No** ☐ **[If Yes, STOP. Project does not qualify as EXEMPT]**

Retrospective Record or Chart Review: Yes ☐ **No** ☐ **(**If "Yes", Please check all that apply)

☐ Retrospective review of medical records: Name of hospital or institution from which records will be obtained:
☐ Employment records ☐ Student records ☐ Other records:

Name of institution or agency from which records will be obtained:

If a non-UNTHSC unit will provide records, attach letter from that agency/clinic.

The data were collected during Time Period (month and year): From _____ To _____

Will the investigators have access to subject identifiers? **Yes** ☐ **No** ☐

Will a "master list" of subject identifiers for this data set be kept? **Yes** ☐ **No** ☐ If yes, for how long? _____
If your protocol calls for a "master list" of identifiers then this may NOT qualify for Exempt. Contact OPHS staff for assistance

Use of existing biological specimens: Yes ☐ **No** ☐ If "Yes", Source of specimens (contact name, entity name and address) and attach description of specimens and origin:

Secondary Data Set Study: Yes ☐ **No** ☐ If "Yes", Answer all questions.

Source of data:
Were the data originally collected for research purposes: **Yes** ☐ **No** ☐ If yes, by UNTHSC researchers? **Yes** ☐ **No** ☐

Is the Source "publicly available"? **Yes** ☐ **No** ☐

Note that "Publicly available" means that the general public can obtain the data. Sources are not considered "publicly available" if access is limited ONLY to researchers. ***NOTE: You must attach a copy of the catalog page/ website page indicating where the dataset can be obtained or located.***

Does the secondary dataset contain personal identifiers? Yes ☐ **No** ☐

Type of identifier (i.e., name, SSN, address, medical record number, etc.):

Public Benefit or Services Programs

Is the study conducted or subject to approval by the federal department or agency head? ☐ **Yes** ☐ **No**

Is the aim to study, evaluate, or otherwise examine one or more of the following [check appropriate box(es)]?

☐ Public Benefit or Service Programs (i.e. Social Security Services, Medicaid, welfare)
☐ Procedures for obtaining benefits or services under those programs
☐ 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

Taste and Food Evaluation

Will this study involve taste evaluation and/or food quality assessment? ☐ **Yes** ☐ **No**

Is the food approved by the Food and Drug Administration (FDA)? ☐ **Yes** ☐ **No [if No, STOP. This does NOT qualify as Exempt]**

Will wholesome (no additives) food be consumed? ☐ **Yes** ☐ **No**

Are the food ingredients at or below the level found to be safe by the FDA? ☐ **Yes** ☐ **No**

Do you ever intend to publish or present (oral, poster or written) the results of this project? Yes ☐ **No** ☐

Is an informed consent needed for this research? Yes ☐ **No** ☐

If yes, this project may NOT be Exempt from Full Board or Expedited IRB review and consideration. Please attach a complete protocol form and synopsis along with this application for further review (see OPHS website for Protocol Form and Summary Format guidelines).

ATTACH TO THIS FORM:

- *Certificate of Human Subjects Training* for **all** study personnel. If such documentation is already on file for *all* key personnel, initial here: _____ [Note that inaccurately claiming that such documentation is on file will significantly delay Review]

(If applicable)

- *Copy of Secondary Data documentation* (examples include: website address or reference information for public use data files; letters of agreement from owners of the dataset, etc.)
- *Copy of Survey or Interview questions* and any research statement or cover letters to be used (if applicable)
- Any other documentation that will assist in a timely review of your project.

SIGNATURES AND ASSURANCE Signature certifies that the Principal Investigator understands and accepts responsibility to ensure that this research and the actions of all project personnel involved in conducting the study will conform to the OPHS-IRB approved protocol, OPHS-IRB requirements/policies and procedures, and all applicable federal regulations.

_____

PRINCIPAL INVESTIGATOR Signature Print Name Date

NOTE: If this is a "Student Project", the Principal Investigator signing above agrees to be fully responsible for all aspects of this project. Ordinarily this person will also serve as the Faculty Advisor for the Student on this project. The Faculty Sponsor / Advisor may designate an alternate Faculty Sponsor / Advisor who will assume responsibilities on a temporary basis, and will notify the OPHS-IRB of any change in the Faculty Sponsor / Advisor for this project.

Student Investigator's Assurance: By my signature as student investigator, I certify the above applicable assurances and that I will meet with my Faculty Sponsor / Advisor on a regular basis to monitor study progress. If my Faculty Sponsor / Advisor is unavailable, I will meet with his/her designated alternate Faculty Sponsor / Advisor who will assume his/her responsibilities. I also agree to notify the OPHS-IRB of any change in Faculty Sponsor / Advisor

_____

STUDENT INVESTIGATOR Signature Print Name Date

Categories of Research that are EXEMPT from Full Board Review ….but must still be evaluated by the OPHS-IRB

(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.

Note: This is an "Information Only" page… Please Do NOT submit this page with the *Request for Review of EXEMPT Category Research Project*