EXEMPT AND LIMITED REVIEW APPLICATION

Form for Exempt and Exempt - Limited Review

For use of this form, see UNCA IRB SOP-3.3 Exempt and Limited Study

Project Title: _____

Principal Investigator (PI): _____ University Affiliated: ☐ Yes ☐ No

Department or Organization: _____ **Phone #:** _____

Email: _____

Co-Principal Investigator (Co-PI): _____ University Affiliated: ☐ Yes ☐ No

Department or Organization: _____ **Phone #:** _____

Email: _____

Student Co-PI (S-Co-PI): _____ University Affiliated: ☐ Yes ☐ No

Email: _____

NOTE: Attach CITI training certificates or other training to the application's IRBNet record. Include a list of additional project personnel, their contact information and CITI certificates.

Proposed Start Date: _____

Types of Data (*Choose All That Apply*)	**Reason for Research Conducted** *(Choose All That Apply)*
____ Primary Data ____ Secondary Data __ Hospital/Clinic chart review __ Purchased Data Base __ Other	____ Faculty Research ____ Undergraduate Course Number: _____ ____ Graduate Course Number: _____ ____ Master Project/Thesis: _____ ____ Student Research Presentation (e.g. UGR) ____ Other: _____
Type of Research *(Choose One)*	
____ Quantitative ____ Qualitative ____ Mixed-Methods	
Research Design *(Choose One)*	**Research Involves External Organization**
____ Experimental ____ Quasi Experimental ____ Non-Experimental	____ No ____ Yes: _____ (Approval Documentation Must be Provided)

I hereby certify that the information provided in this request form is complete and accurate. As the principal investigator, I have ultimate responsibility for the conduct of this research project, the ethical performance of the project, the protection of the rights and welfare of human participants, and strict adherence to any stipulation designated by the IRB.

Upon approval of this request by the IRB, the proposed research project fully complies with at least one of the categories of exempt but limited review research outlined in The Code of Federal Regulations governing research with human subjects, 45 CFR §46.101 (b).

Principal Investigator's Signature Date (MM/DD/YYYY)

I. Brief Project Introduction/Overview

Please provide a brief statement of purpose, significance of study, and relevant supporting literature.

II. Research Question and/or Research Hypothesis

Please provide research questions

III. Screening Questions: Does Exempt Review Apply?

Yes	No	
☐	☐	1. Will the research expose participants to discomfort or distress beyond levels encountered in daily life (i.e., does research involve more than minimal risk)?
☐	☐	2. Will the collected data include identifiers which could be potentially damaging to a participant's financial standing, employability or reputation (e.g. could be fired if it were known they participated in the research or if they could be linked to specific responses)?
☐	☐	3. Will your research participants include pregnant women (where the research would put the pregnancy or fetus at risk), prisoners, cognitively, economically, or educationally impaired participants?
☐	☐	4. Does the research involve focus groups?*
☐	☐	5. Does the research include any video recording or photographing?**
☐	☐	6. Does any part of the research require deception or incomplete disclosure of information to your participants? *
☐	☐	7. Does the research involve minors? ***

If you answered YES to any of the screening questions above, your application does NOT qualify for exempt review. STOP COMPLETING THIS FORM and complete the "Expedited or Full Board Protocol Application" for IRB review.

*Some studies involving focus groups manner or deception are acceptable. If you believe that your study falls under these parameters please consult with the IRB Chair.

** In certain circumstances, researchers may use recordings for exempt categories 2 & 3.

*** Exempt categories 1 & 4-8 can be applied to research with children, while category 2(i) and 2(ii) only applies to research when the research involves educational tests or the observation of public behavior if the investigator(s) do not participate in the activities being observed.

IV. Exempt Research Categories

Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from IRB review. Below are the categories of exempt research outlined in 45 CFR §46.101 (b). Go to https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101 for more details.

Mark all categories that apply to the proposed research activity and state in the space below each category how this research is consistent with the selected categories. **You should attach any supporting documents to this form as needed.**

☐ **(1) Educational Settings**

Research conducted in established or commonly accepted educational settings, involving normal educational practices, and are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction, 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.

(Examples: Evaluating the use of accepted or revised standardized tests / Testing or comparing a curriculum or lesson / A program evaluation of pharmacy continuing education)

☐ **(2) Educational Tests, Surveys, Interviews or Uninfluenced/Unmanipulated Observation of Public Behavior**

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or uninfluenced/unmanipulated observation of public behavior (including auditory or visual recording).

At least **one** of the following criteria must be met:

(i) ☐ human subjects cannot be identified, directly or through identifiers

(ii) ☐ 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, or reputation

(iii) ☐ Subject to Limited Review - identity can be ascertained

(Examples: Surveying teachers, nurses, or doctors about a technique or an outcome / Interviewing managers about a management style or best practice / Conducting a focus group about an experience or an opinion of a community program)

☐ **(3) Benign Behavioral Interventions (BBI) with Adults**

BBI are defined as "being brief in duration, harmless, painless, not physically invasive, not likely to have a significant lasting impact on subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing." This is done in conjunction with the collection of information through verbal or written responses or audiovisual recording if the participant agrees to the intervention and information collection and at least one of the below listed criteria is met. This allows for collection of

	potentially sensitive or harmful identifiable private information from adults if there are adequate provisions for protecting privacy and maintaining confidentiality. At least **one** must be met: (i) ☐ identity cannot be ascertained directly or through identifiers (ii) ☐ any disclosure of responses outside the research would not reasonably place the subjects at risk of criminal/civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation (iii) ☐ Subject to Limited Review - the information obtained is recorded by the investigator in such a manner that the identity of the subjects can be ascertained directly or through identifiers **All** of the following must be true: (i) This is behavioral research. (ii) Participants are adults. (iii) If there is deception, the participants give consent to the deception. (iv) The above definition of BBI is met (v) There are adequate provisions for confidentiality and privacy if there is potentially sensitive/harmful information (vi) interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Examples: (solving puzzles under different noise levels, playing an online game, having them decide how to allocate a nominal amount of cash between themselves and someone else)
☐	**(4) Exemptions for Secondary Research (4, 7, 8 – Subject to Limited Review)** Secondary research that uses identifiable private information or identifiable bio specimens. At least **one** of the following criteria must be met: (i) ☐ the identifiable information is publicly available (ii) ☐ the information, including that for bio specimens, is not readily identifiable directly/through identifiers; the investigator does not contact the subjects; investigator will not re-identify subjects (iii) ☐ research involves only information collection and analysis involving 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); (iv) ☐ The research is conducted by/on behalf of a Federal department or agency using government-generated or government-collected information obtained for non-research 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 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq. **If this is an identifiable bio specimen or uses identifiable private information, there must be documentation of consent.** The following must be true: (i) 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. (ii) 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. Attach the following documents for limited review: *1.* broad consent for the storage, maintenance, and secondary research in accordance with §46.116(a)(1) through (4), (a)(6), and (d); *2.* documentation of informed consent or waiver of documentation of consent in accordance with §46.117 *(Examples: Analyzing existing tissue samples or data set which are recorded by the investigator without identifiers)*
☐	**(5) Research by a Federal Agency** Research and demonstration projects which are conducted by or supported by a Federal 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 following **must** be true: (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects. (Examples: internal studies by Federal employees, studies under contracts or consulting arrangements, cooperative agreements, or grants)
☐	**(6) Taste and Food Quality Evaluation**

	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 (iii) 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.

SUPPLEMENTAL MATERIAL FOR LIMITED REVIEW

(Complete supplemental form only if 2(iii), 3(iii) and/or 4 were checked)

V. Instruments (Attach all instruments to be used)

Please briefly describe all means used to collect data.

VI. Procedures / Methodology

Describe the data collection process:

VII. Data Confidentiality

a. Does this data fall within:

_____ Public Domain
(Ex: public record document, public access documents, court transcripts, etc.)

____ Confidential Domain
(Ex: data only accessible by through permission of the institution and/or subject being studied)

b. Data Access

*Please describe **all parties** who will have access to the data.*
Please provide (in an attachment) evidence of human subject training/confidentiality agreement for those who have access.

c. Subjects' Anonymity/Confidentiality

Indicate if the existing data collection includes identifiable information about subjects, and how the data is de-identified.
(The subjects in the existing data collection must not identified to qualify for exempt category 45 CFR §46.101 (b)(4))

d. Data Storage

How, where and for how long will the data be stored? (Please note that for IRB purposes all data must be stored for a minimum of three years.)

If conducting Secondary Research, will there be storage or maintenance of identifiable private information or identifiable bio specimens for potential secondary research?
YES NO

If yes, have the subjects given "broad consent" for this?

YES NO

e. Data Deletion

How will the data be destroyed? (Please address all data sources, e.g. video, audio-visual, interview, questionnaires, consent forms, electronic data, etc.)