HARDING UNIVERSITY
INSTITUTIONAL REVIEW BOARD

Request for Exemption from IRB Review

Date:

Proposal Number:
(to be assigned by IRB administrator)

Submit this completed form to the IRB as an email attachment: irb@harding.edu.

Title of Project:

Name and contact information for the Principal Investigator:

H # (if applicable)

I request exemption from IRB approval for my project. The basis upon which I claim my exemption is (mark one):

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

☐ 2. Research that only includes 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 subjects can be identified, directly or through identifiers linked to the subjects; and
   b. 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 and the disclosure of the subjects' responses outside the research would not reasonably be damaging to the subjects' "educational advancement."
   c. where identifiable information (even if sensitive) is recorded, provided that an IRB determines through limited review that, when appropriate, there are adequate privacy and confidentiality protections in the study.

☐ 3. Research involving benign behavioral interventions with adults who prospectively agree to the research, when the information collected is limited to verbal or written responses, including data entry or audiovisual recordings.
   a. the information recorded cannot be readily linked back to the subjects in such a manner that subjects' identity can be readily ascertained, directly or through identifiers linked to the subjects; or
   b. any disclosure of this information would not place the subjects at risk of certain harms, or
   c. the information is recorded in an identifiable manner, even if sensitive, provided that an IRB determines through limited review that, when appropriate, there are adequate privacy and confidentiality protections in the study.

☐ 4. Secondary research use of identifiable private information in existing data or identifiable biospecimens. a research study that proposes to analyze samples or information that will be collected for clinical purposes in the future could qualify for this exemption if it meets at least one of the applicability provisions.

a. when the identifiable materials are publicly available, or
b. when the information is recorded by the investigator in a nonidentifiable manner [the investigator must not attempt to re-identify or contact the research subjects]
c. when the investigator's secondary use of the identifiable private information is regulated under HIPAA as "healthcare operations," "research," or "public health." [Note that HIPAA does not apply to biospecimens, so this provision applies only to the secondary use of identifiable private health information (which can include information obtained from biospecimens).]
d. When the secondary research is conducted by or on behalf of a federal department or agency, using data collected or generated by the government for non-research purposes, and the information is subject to federal privacy standards and other requirements specified in the exemption.

☐ 5. Research and demonstration projects which are designed to study, evaluate, or otherwise examine:

a. public benefit or public service programs, if the research is conducted or funded by a federal department or agency. [the federal entity conducting or sponsoring the research to publish a publicly available list of the projects that are covered by this exemption before the research begins.]
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

☐ 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

☐ 7. Research with materials originally obtained for non-research purposes or for research other than the current research proposal (secondary research) with broad consent from the subjects for the storage, maintenance, and secondary research use of their identifiable materials.

☐ 8. Secondary research use of identifiable private information or identifiable biospecimens originally obtained for non-research purposes or for research other than the current proposal.

a. broad consent must be obtained from the subjects for the secondary research use of their identifiable materials,
b. documentation or waiver of documentation of informed consent must be obtained,
c. an IRB must conduct a limited review to make certain determinations relating to privacy and confidentiality protections and broad consent,
d. investigators cannot include the return of individual research results to subjects in the study plan. [Note that this requirement does not limit an investigator's ability to abide by any other legal requirement to return individual research results.]

I have attached a one-page synopsis of my project.

Signature of Principal Investigator _____ **Date** _____