Form 3: Application for Exemption for UAH Institutional Review Board

Name:_____ Date:_____

Address:_____
City, State, Zip

Telephone: ( )_____ UAH Email:_____

PI and Faculty Supervisor Signature(if applicable):

Signature:_____ Date:_____

Signature:_____ Date:_____

This checklist must accompany all IRB applications requesting exempt review. Check all categories, as defined by 45 CFR 46.104(d), that apply to the proposed research project.

Exempt Categories

Please check one or more of the categories below:

☐ 1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instruction strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. This category does not apply to Food and Drug Administration (FDA) regulated research.

☐ 2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(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, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked

to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

The first two criteria of this category (i and ii) may not be applied to research with minors when involving surveys and/or interviews. They may only be applied to research with minors when involving educational tests or the observation of public behavior and the investigators do not participate in those activities. The third criteria of this exemption (iii) may not be applied to research with minors.

☐ 3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) 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, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

For the purpose of this provision, benign behavioral 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. UAH defines brief duration for an intervention (not including data collection, unless intertwined) as lasting no longer than a few minutes to a few hours on a single day. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Research involving minors is not eligible for this category of exemption and this category does not apply to FDA regulated research.

☐ 4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens that have been or will be collected for a nonrelated primary or initial activity, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or

through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the 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); or

(iv) The research is conducted by, or 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.

Note: This category may not be applied to research involving primary collection from subjects; collection must be performed for a non-related purpose. Collection can be either prospective or retrospective. This category does not apply to FDA regulated research.

☐ 5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website 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.

☐ 6. Taste and food quality evaluation and consumer acceptance studies, if:

(i). wholesome foods without additives are consumed or
(ii). 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.

(Approved by the Office of Management and Budget under Control Number 0990–0260)

I hereby certify that my research fully meets the categories indicated above. In the event that my research becomes ineligible for such exemption(s) for any reason, I will re-apply for appropriate UAH IRB review.

Signature: _____ Date: _____

Checklist: *New, Exempted* Review Submission

Documents must be saved in pdf format and sent to

irb@email.uah.edu.

☐ Completed and electronically signed IRB **Application for Exemption from Review by the UAH IRB**

☐ One copy of the signed Institutional review board application (Form 1).

☐ For research involving children and/or minors less than 19 years of age, one copy of a memorandum from the Principal Investigator which must address the Children's Risk Level assessment (see **Form 6** at (http://www.uah.edu/irb)

Make sure you have checked the IRB web page

(http://www.uah.edu/irb)

for the most current consent form format.

Submit all materials in electronic form to irb@email.uah.edu.