Appendix A. Exempt Review

A. Applicability

The procedures outlined in this Appendix apply to all human subject research that is Exempt from review under federal regulation 45 CFR 46.

B. Exempt Research

As described in the Code of Federal Regulations (Title 45, Part 46, Section 104), research activities that fall into one or more of the following categories, and in which prisoner subjects are only incidentally included as a part of a broader subject population, may be determined to be exempt from human subject protections outlined in 45 CFR 46.104. All research studies, including those determined exempt, conducted under the auspices of EMU are still subject to applicable portions of this policy as well as all other applicable EMU policies and procedures and state law.

1. Research conducted in established or commonly accepted educational settings, involving 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 instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research that only includes interactions involving the use of 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:

    a. Information obtained is recorded by the investigatorin such a manner that human subjects cannot be readily 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 human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a limited IRB review to make the determination required by 45 CFR 46.111(a)(7).

NOTE: This exemption may apply to minors for paragraphs a and b involving only educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Paragraph c may not involve 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; OR

   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.

   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 they will be unaware of or misled regarding the nature or purposes of the research.

   NOTE: This exemption is not applicable to minors.

4. Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens if at least one of the following criteria is met:

   a. The identifiable private information or identifiable biospecimens are publicly available; OR

b. 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; OR

c. 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

d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch 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*.

5. Research and demonstration projects which 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.

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. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable

biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 45 CFR 46.111(a)(8).

8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use if the following criteria are met:

    a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.116(a)(1) through (4), (a)(6), and (d); AND

    b. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR 46.117; AND

    c. An IRB conducts a limited IRB review and makes the determination required by 45 CFR 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 a of this section; AND

    d. 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.

C. Exempt Review

Research projects that meet the specifications defined in 45 CFR 46.104 may qualify for exemption. These studies are not subject to federal regulations specified in 45 CFR 46 but are subject to all other applicable federal laws and regulations, state law, local law, and university policy. Research involving prisoners (unless prisoners are only incidentally included in a broader study population) and FDA-regulated research that does not otherwise qualify for exemption under 45 CFR 46.104 may not be Exempt. Similarly, research involving surveys, interviews, or public observation of children may not be Exempt except for public observation research involving educational tests or public observation of children in which the investigator does not participate in the activities being observed.

All Exempt research that does not require a limited IRB review per 45 CFR 46.104(d)(2)(iii), (d)(3)(i), (d)(7), or (d)(8) will be reviewed in the Office of Research Compliance. The UHSRC administrator will review all Exempt research submissions and is responsible for all correspondence, including issuing a determination letter, with the principal investigator. Investigators are not permitted to determine their own exemption.

Exempt research will be reviewed according to the following ethical criteria:

1. The research presents no greater than minimal risk to subjects;

2. Subject selection, if applicable, will be equitable and not coercive;

3. Data confidentiality will be protected. If subject identity will be disclosed in publication, the subject will be adequately informed and given the opportunity not to be identified; and

4. If there are interactions with subjects, the following information will be disclosed to subjects prior to enrollment:

    a. That the investigator is a researcher conducting a research study;

    b. All study procedures involving the subject;

    c. Any risks that may be involved with participation;

    d. How data will be kept confidential. If the investigator wishes to identify subjects in publication, each subject will individually be given the option to remain anonymous;

    e. That participation is voluntary;

    f. That at any point, the subject can refuse to participate or go "off the record" during the study; and

    g. Contact information for the principal investigator and the UHSRC.

If the reviewer decides they need additional information, the reviewer will issue a revision request letter to the principal investigator. Once that information has been received and the reviewer is satisfied, the reviewer will make an Exempt determination and designate the Exempt type/categories. The reviewer will send the Exempt determination letter to the principal investigator.

Changes to Exempt research will be reviewed by the UHSRC administrator to determine that the study remains Exempt. If the change causes the study to no longer qualify for exemption, the entire study will be reviewed by the UHSRC, either under Expedited review or at a convened meeting, whichever is deemed appropriate.