CATEGORIES OF EXEMPT RESEARCH

The LSUHSC IRB currently recognizes only Exempt Categories 1-6. Research falling under Categories 7 & 8 should be submitted for review by the Expedited procedure.

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, so long as the research is not likely to adversely affect students' opportunity to learn the required educational content or the assessment of educators who provide instruction. This includes:
(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.

This exemption applies ONLY to investigations of normal educational practices in regular educational settings. Surveying or interviewing participants may apply under this category IF the queries are about education instructional strategies, techniques, curriculum 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 (including visual or auditory recording) uninfluenced by the investigator, as long as:
(a) the information obtained is recorded in such a manner that the identity of the subject 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 in such a manner that the identity of 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

*Research involving **interventions** in addition to the educational tests, survey/interview procedures, or observation of public behavior do not qualify for this exemption. Examples of such non-qualifying research activities include:*

- *Collection of biospecimen (e.g., a cheek swab), in addition to collecting verbal or written responses to questions*
- *Randomly assigning students to take an educational test in a quiet room or in a room with a moderate level of noise, or to consume a snack (or not) before taking the test*
- *Observation of public behavior after an intervention, for example, offering individuals an ostensibly lost wallet to see if they will accept it*

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 is met:
(a) the information obtained is recorded in such a manner that the identity of the 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 in such a manner that the identity of 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.

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. Examples include having subjects:

- *play an online game,*
- *solve puzzles under various noise conditions, or*
- *decide how to allocate a nominal amount of received cash between themselves and someone else.*

*This exemption is not applicable if the research involves **deception** unless the subject authorizes the deception by prospectively agreeing to participate in research after being informed that he or she will be unaware of or misled regarding the nature or purposes of the research.*

Subjects must be adults but provision does not specify that they must be competent, and therefore tests of competency are not necessary.

4. Secondary research involving the use of identifiable private information or identifiable biospecimens when consent is not required, if:

(a) the identifiable private information or biospecimens are publicly available; **OR**

(b) the information is recorded in such a manner that the identity of subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator will not contact the subjects, and the investigator will not re-identify subjects; **OR**

(c) the use of identifiable health information is regulated under 45 CFR parts 160 and 164 (the HIPAA Privacy Rule), 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,

i. 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,

ii. 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**

iii. 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.

This exemption applies to information and biospecimens that have already been collected AND those that do not yet exist when the research study is proposed for exemption (i.e., that could be collected, for purposes not related to the proposed research study, in the future).

Unlike Exemption Categories 7 & 8, this exemption does not depend on any consent requirements imposed by the Common Rule being met.

This exemption permits the secondary research use of identifiable private information or identifiable biospecimens obtained from subjects who are prisoners, if the research is not designed in a way that seeks to recruit prisoners as a population but rather only incidentally (i.e., not intentionally) includes prisoners.

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) that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including, but not limited to:

(a) procedures for obtaining benefits or services under those programs; **OR**

(b) possible changes in, or alternatives to, those programs or procedures, **OR**

(c) possible changes in methods or levels of payment for benefits or services under those programs.

This exemption applies to research a federal department or agency itself administers or conducts through its own employees or agents, AND also to research it supports through a grant or contract program. Therefore, the exemption applies to research and demonstration projects supported through, for example, federal grants or cooperative agreements.

6. Research evaluating taste and food quality and consumer acceptance, if the food being consumed:
(a) is wholesome and does not contain additives; **OR**
(b) contains a food ingredient at or below the level, and for a use, 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; **OR**
(c) contains agricultural, chemical or environmental contaminant(s) at or below the level found to be safe, by the three agencies listed above.

7. Storage or maintenance of identifiable private information or identifiable biospecimens collected under a broad consent for use in secondary research.

This exemption requires that an IRB conduct limited IRB review to make the following determinations (required by §___.111(a)(8)):

- *Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §___.116(a)(1)–(4), and (a)(6), and (d);*
- *Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §___.117; and*
- *If a change is made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, adequate provisions must be in place to protect the privacy of subjects and to maintain the confidentiality of data.*

Examples of potential changes made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained include the following:

- *if information or biospecimens are moved from one electronic or physical storage location to another due to considerations related to research plans;*
- *if information or biospecimens will be stored for longer than they otherwise would have been for the original purpose;*
- *if information or biospecimens are placed in a research registry or repository created to serve as a resource for investigators; or*
- *investigators are given electronic or physical access to the information or biospecimens.*

8. Secondary research involving the use of identifiable private information or identifiable biospecimens collected under a broad consent.

This exemption is applicable if:

- *broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §___.116(a)(1)–(4), (a)(6), and (d);*
- *documentation of informed consent or waiver of documentation of consent was obtained in accordance with §___.117;*
- *an IRB conducts a limited IRB review to make the determination required by §___.111(a)(7), and to make the determination that the research to be conducted is within the scope of the broad consent; and*
- *the investigator does not include returning individual research results to subjects as part of the study plan. However, it is permissible under this exemption to return individual research results when required by law regardless of whether or not such return is described in the study plan.*