## TCSP IRB Categories of Review

Review the categories to determine whether your research is eligible for Expedited or Exempt review.

### Expedited Categories

Federal regulations provide that certain types of research may be considered for review through an expedited process (45 CFR 46.110). Click here for additional information. A primary criterion for expedited review is that the research be of minimal risk. The Office of Human Research Protections (OHRP) defines minimal risk as risk where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than that ordinarily experienced in daily life or during the performance of routine physical or psychological examinations. In addition, the purpose of the research must fit within a series of categories as stipulated by DHHS regulations.

A. The research activity poses no greater that minimal risk; and
B. The identification of the participant and/or their responses would not reasonably place the participant at risk of criminal or civil liability or be damaging to the participant's financial standing, employability, insurability, reputation, or be stigmatizing, unless appropriate protections will be implemented so that the risk related to invasion of privacy and breach of confidentiality are no greater than minimal; and
C. The project falls under one of the expedited categories.
    1. *Clinical studies of drugs and medical devices only when condition.
    2. [1]Collection of blood samples by finger stick, heel stick, ear stick or venipuncture from (a) healthy, nonpregnant adults who weigh at least 110 lbs; (b) other adults and children.
    3. *Prospective collection of biological specimens for research purposes by noninvasive means.
    4. *Collection of data through noninvasive procedures (not involving anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. For example :…(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
    5. Research involving materials (data, documents, records or specimens) that have been collected solely for non-research purposes (such as medical treatment or diagnosis.
    6. Collection of data from voice, video, digital or image recordings made for research purposes.
    7. Research on an individual or group characteristics or behavior (including but not limited to research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

### Exempt Categories

1. Research conducted in established or commonly accepted educational settings, that specifically involve normal educational practices such that are not likely to adversely impact

[1] For additional information please see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101

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 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; **or 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 .111(a)(7).

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 interventio**n and information collection and at least one of the following 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 subject, and an IRB conducts a limited IRB review to make the determination required by § ll.111(a)(7). Children cannot be included.

   *Benign Behavioral Intervention is 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.

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: 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 [HIPAA], 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 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