Exempt Review Categories – Effective 1/21/19

A project is identified as **exempt** if the project:

1. involves no more than minimal risk (*Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests) **and**
2. only involves human subjects (or materials of human origin) in one or more of the following categories:

EXEMPT	
Category	***Description of Human Subject Research Activities***
1	Research, conducted in **established or commonly accepted educational settings, that specifically involves normal educational practices** that are not likely to adversely impact students' opportunities to learn required educational content or the assessment of educators who provide instruction. This includes most: 1) research on regular and special education instructional strategies or 2) 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.** 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, or reputation. *(Also see Expedited category 7.)*[1] **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 adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of the data.
3	Research involving **benign behavioral interventions**[2] 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, or reputation. *(Also see Expedited category 2-7.)*[1] **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 adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of the data.

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; 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 the subjects; 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 for purposes of "health care operations" or Research" as 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. (Additional stipulations apply.)
5	Research and demonstration **projects that are conducted by or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads,** and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including; 1) procedures for obtaining benefits or services under those programs; 2) possible changes in or alternatives to those programs or procedures; or 3) possible changes in methods or levels of payment for benefits or services under those programs.
6	**Taste and good quality evaluations and consumer acceptance studies**, if wholesome foods without additives are consumed or 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 FDA or approved by the EPA/USDA.

[1] Category 2 **cannot** be used for research involving children, except for use of educational tests (cognitive, diagnostic, aptitude, achievement) or research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Children are defined in the HHS regulations as "persons who have not yet attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

Categories 1 through 6 **cannot** be used for classified research or research involving prisoners, except for research aimed at involving a broader subject population that only incidentally includes prisoners.

Categories 1 through 5 **cannot** be used for research to which FDA regulations and policies apply.

[2] 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, 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.

Category 3 cannot be used for deception studies, 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.

Expedited Review Categories

A project is eligible for **expedited review** if it involves:

1. no more than minimal risk (*Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests) **and**
2. only involves subjects (or materials of human origin) in one or more of the following categories:

Expedited Review	
Category	***Description of Human Subject Research Activities***
1	**Clinical studies of drugs and medical devices only when** (a) research on drugs for which an investigational new drug application is not required. Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review. **Or** (b) research on medical devices for which (i) an investigational device exemption application is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
2	**Collection of blood samples** by finger stick, heel stick, ear stick, or venipuncture as follows: (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or (b) from other adults and children[1], considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3	**Prospective collection of biological specimens for research purposes by noninvasive means.** Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (I) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
4	**Collection of data through noninvasive procedures** (not involving general anesthesia or sedation) routinely employed in clinical practice, **excluding procedures involving x-rays or microwaves.** Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indication.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging (MRI); (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of individual.

Expedited Review Categories

Expedited Review	
Category	***Description of Human Subject Research Activities***
5	**Research involving materials** (data, documents, records, or specimens) **that have been collected, or will be collected solely for nonresearch purposes** (such as medical treatment or diagnosis). *(Also see Exempt from Full Board Review category 4)*
6	**Collection of data from voice, video, digital, or image recordings made for research purposes.**
7	**Research on 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.** *(Also see Exempt from Full Board Review category 2)*
8	**Continuing review of research previously approved by the convened IRB as follows:** (a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or (b) Where no subjects have been enrolled and no additional risks have been identified; or (c) Where the remaining research activities are limited to data analysis.
9	**Continuing review of research,** not conducted under an investigational new drug application or investigational device exemption where categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

[1] Children are defined in the HHS regulations as "persons who have not yet attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

Categories 1 through 9 cannot be used for classified research or research involving prisoners.

For research in **Expedited category**

- The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal