Institutional Review Board
Types of Review

The specific type of review needed depends upon the level of risk inherent in the proposal. There are three options: 1. Exempt review, 2. Expedited review, and 3. Full review. Classifications and definitions of the types of review are guided by the Office for Human Research Protection (OHRP), Federal Department of Health and Human Services (HHS).

1. **Exempt Review.**

Proposals that fall under the exempt guidelines are reviewed by the SMUIRB chair or the chair designee. Since exempt studies are not reviewed by the full SMUIRB, exempt review can be submitted at any time. However, if your study is determined to be appropriate for expedited or full review instead, the study proposal will be routed for the appropriate review process, and the principal investigator(s) will be notified about the change of review status.

The federal guidelines for exemption include:

A) **Research in Established or Commonly Accepted Educational Settings**

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 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 (HHS 2017).

B) **Educational Tests, Surveys, Interviews, or Uninfluenced/ Unmanipulated Observation of Public Behavior**

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 participants cannot readily be ascertained, directly or through identifiers linked to the participants;

ii) Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' 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 participants can readily be ascertained, directly or through identifiers linked to the participants, and the SMUIRB conducts a limited IRB review to make the determination (HHS 2017).

C) **Benign behavioral interventions in conjunction with the collection of information from an adult**

Research involving benign behavioral interventions in conjunction with the collection of information from an adult participant through verbal or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to the intervention and information collection and 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 participants cannot readily be ascertained, directly or through identifiers linked to the participants;

ii) Any disclosure of the participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' 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 participants can readily be ascertained, directly or through identifiers linked to the participants, and the SMUIRB conducts a limited IRB review to make the determination.

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 participants, and the investigator has no reason to think the participants will find the interventions offensive or

embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the participants 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 participants regarding the nature or purposes of the research, this exemption is not applicable unless the participant authorizes the deception through a prospective agreement to participate in research in circumstances in which the participant is informed that he/she/they will be unaware of or misled regarding the nature or purposes of the research (HHS 2017).

D) **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 participants cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants;

iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information, for the purposes of “health care operations” or “research”; 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, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995. (HHS 2017).

E) **Research and demonstration projects that are conducted or supported by a Federal department or agency**

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.

Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site 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 participants (HHS 2017).

F) **Taste and food quality evaluation and consumer acceptance studies**

Taste and food quality evaluation and consumer acceptance studies:

i) If wholesome foods without additives are consumed, or
ii) 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 (HHS 2017).

G) **Storage or maintenance for secondary research for which broad consent is required**

Storage or maintenance of identifiable private information or identifiable bio-specimens for potential secondary research use if the SMUIRB conducts a limited IRB review and makes the determinations (HHS 2017).

H) **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:

i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained;
ii. Documentation of informed consent or waiver of documentation of consent was obtained;
iii. SMUIRB conducts a limited IRB review and makes the determination that the research to be conducted is within the scope of the broad consent; and
iv. The investigator does not include returning individual research results to participants as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results (HHS 2017).

2) **Expedited review.**

Research activities that (1) present no more than minimal risk to participants, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the SMUIRB through expedited review. The expedited studies are reviewed by two individual SMUIRB members rather than the full SMUIRB. Protocols that qualify for expedited review can be submitted at any time. However, if your study is determined to be appropriate for exempt or full review instead, the study proposal will be routed for the appropriate review process, and the principal investigator(s) will be notified about the change of review status.

Expedited categories include:

i) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application is not required. (Note: 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.)

(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.

ii) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these participants, the amounts drawn may not exceed 550 ml in an eight (8) week period and collection may not occur more frequently than two (2) times per week; or

(b) from other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an eight (8) week period and collection may not occur more frequently than two (2) times per week.

iii) Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a non-disfiguring 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) un-cannulated 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.

iv) 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 indications.

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 participant or an invasion of the participant's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (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 the individual.

v) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of participants. This listing refers only to research that is not exempt.)

vi) Collection of data from voice, video, digital, or image recordings made for research purposes.

vii) 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.

viii) Continuing review of research previously approved by the convened SMUIRB as follows:

(a) where (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; or

(b) where no participants have been enrolled and no additional risks have been identified; or

(c) where the remaining research activities are limited to data analysis.

ix) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the SMUIRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

3) **Full review**

A full SMUIRB review is required if a research protocol does not qualify for "exempt" or "expedited" review. Studies for full review should be submitted by the first working day of the calendar month to be reviewed during the SMUIRB meeting held that month, which is usually during the second or third week of the month. As soon as the proposal is received, briefly reviewed, and accepted by the SMUIRB administrator, the proposal is distributed to all SMUIRB members for individual review in preparation for a full review at the monthly meeting. At the monthly SMUIRB meeting, the research proposal will be brought forth for discussion among members of SMUIRB to assure all aspects of the study are in full compliance with federal human subject protection guidelines established by the department of Health and Human Services (HHS). The study may receive one of the following decisions:

1. Approve, as is, with no modifications
2. Approve with minor modifications (revisions submitted to SMUIRB Chair review only)
3. Approve with major modifications (revisions submitted for full SMUIRB review)
4. Do not approve (the proposal may not be resubmitted to the SMUIRB).

The SMUIRB does not meet during the months of August and December.