SAMUEL MERRITT UNIVERSITY

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**. Proposals that fall under the exempt guidelines are reviewed by the IRB chair. Since exempt studies are not reviewed by the full IRB, exempt review can be submitted at any time. However, if your study does not quality for exempt review, it will automatically be reviewed at the next scheduled meeting of the IRB. The federal guidelines for exemption include:

    a) Research which is conducted in established educational settings, involving standard practices such as i) research on routine or special education instructional strategies, or ii) research that compares types of techniques, various curricula, or management methods used in the classroom.

    b) Research which employs the use of cognitive, diagnostic, aptitude, or achievement educational tests, procedures using survey or interview or observation of public behavior unless the following apply: (i) the information that is obtained is recorded in a way that identifies human subjects either directly or via identifiers linked to the subjects; and (ii) any disclosure of the responses of the subjects outside the research can reasonably place the subjects at risk of civil or criminal liability, or cause damage to the subject's reputation, financial standing, or ability to be employed.

    c) Research which employs the use of cognitive, diagnostic, aptitude, or achievement educational tests, procedures using survey or interview or observation of public behavior that is not exempt in section 2 above if (i) the human subjects are public officials who have been either elected or appointed or candidates for public office; or (ii) federal statute(s) require(s) without exception that information that may be personally identifiable will be maintained in a confidential manner throughout the research and thereafter.

    d) Research which involves the collection or study of the following: existing data; records, documents, and pathological or diagnostic specimens, if such are publicly available or if the needed

information is recorded in such a manner that subjects cannot be identified either directly or via identifiers linked to the subjects.

e) Research and demonstration projects which are either subject to the approval of or conducted by the (federal) department or agency heads, and which are designed to study, evaluate or in some way examine the following: (i) public benefit or service programs; (ii) procedures that explain how benefits or services under those programs will be obtained; (iii) possible alternatives to or any changes in those procedures or programs; (iv) possible changes in methods or levels of payment for either services or benefits under those programs.

f) Studies of taste and food quality evaluation and consumer acceptance, (i) if foods that are wholesome and without additives are consumed; (ii) if a food is consumed that contains a food ingredient found to be at or below the level and for a use which has been found to be safe, or agricultural chemical or environmental contaminant at or below a safe level, as proclaimed by the FDA or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

2. **Expedited review**. Some studies qualify for expedited review (review by two individual IRB members rather than the full IRB). Protocols that qualify for expedited review can be submitted at any time. However, if it turns out that your study does not quality for expedited review, it will automatically be reviewed at the next scheduled meeting of the IRB. Expedited categories include:

a) Minor modifications to approved protocols. (Examples include: advertisements, changes in compensation, grammatical or organizational changes in consent forms, adding an investigator who has already been approved by the SMUIRB for another study to an already approved study.)

b) Studies that involve no more than minimal risk of harm, and are not targeted to a population with limited capacity to consent, and involve procedures included on the OHRP list of procedures for which expedited review may be used.

i) collection of hair, nail clippings, teeth, etc.

ii) collection of excreta and external secretions

iii) recording of data using non-invasive procedures

iv) collection of small blood samples (450 ml in eight-week period - no more than two times per week)

v) voice recordings

vi) moderate exercise by healthy volunteers

vii) study of data, records and specimens

viii) research on individual or group behavior

ix) research on drugs or devices for which an IND or IDE exemption is not required

x) items from exempt list that have been upgraded

xi) any other category added by the DHHS and published in the Federal Register.

3. **Full review** requires review and discussion at a regular meeting of the SMUIRB. Full review is required if a research protocol does not qualify for "exempt" or "expedited" review. Studies for full review should be submitted the first working day of the calendar month.