Institutional Review Board for the Protection of Human Subjects

The Samuel Merritt University Institutional Review Board (SMUIRB) reviews research projects to ensure that two broad standards are upheld: first, that subjects are not placed at undue risk; and second, that they give uncoerced, informed consent to their participation. With representation from a wide range of scientific disciplines and from outside the academic community, the IRB gives timely but individualized attention to the numerous research projects at the University. A project is first reviewed in its proposal stage, before subjects are recruited. Each approved project is reevaluated on a continuing basis. The IRB works with investigators to modify projects to ensure adequate protection for its subjects' welfare and right of self-determination.

Samuel Merritt University's process for protecting human research subjects reflects federal regulations developed in response to such cases as the Tuskegee syphilis study and the U.S. Army's radiation experiments. The Department of Health and Human Services' Office for Human Research Protections (OHRP) oversees the operation of the IRB. The Food and Drug Administration (FDA) enforces regulations for the use of experimental drugs and devices.

We will make every effort to make the IRB review process as simple as possible and hope that you will find the process beneficial. You can assist in facilitating the approval of your proposal by following the directions outlined below. **Please take the time to read this entire section; it will save you time.** You are encouraged to contact Ms. Jamie Hirota, IRB Administrator, (510) 869-6647, with specific questions prior to submitting your application for review. It is important to remember that failure to follow these directions carefully can delay the approval process. We look forward to approving your IRB proposal!

DO YOU NEED TO APPLY FOR IRB APPROVAL?

Regardless of how research is funded, any University research requires IRB review if:

- it uses humans, human tissue, or data gathered on human subjects; and
- it is performed **by University faculty, students, or staff**; **on University premises; with University equipment**; or **on University faculty, students, or staff**.
- it is performed by **University faculty, students, or staff at Alta Bates Summit Medical Center**. **NOTE: You must also get IRB approval from Alta Bates Summit Medical Center, and submit proof of Alta Bates Summit IRB approval to the Samuel Merritt University IRB.**

The scope of review encompasses research in the social and behavioral sciences as well as in the health and biological sciences.

Investigator's Obligations

According to the Operating Policies and Procedures for the Samuel Merritt University Institutional Review Board, investigators will:

1. Assume responsibility for acquiring the information necessary to fully comply with SMUIRB, United States Department of Health and Human Services (USDHHS), and Food and Drug Administration (FDA) regulations.

2. Submit a proposal to the SMUIRB for any and all research using human subjects.

3. Ensure the proposal is complete and truthful prior to submission for review by the SMUIRB.

4. Comply with any and all SMUIRB, USDHHS, and FDA regulations.

5. Notify the SMUIRB of any member of the investigative team who is not in compliance with an approved SMUIRB protocol.

6. Provide timely reports to the SMUIRB of any adverse effects that occur while the research is being conducted.

7. Provide timely reports to the SMUIRB of any deviation from the protocol that could affect the rights and welfare of human subjects.

8. Provide continuing review reports to the SMUIRB at intervals designated by the SMUIRB.

9. Submit a final report when the research project is complete.

WHERE TO START

All forms and documents are located on the University's website at http://www.samuelmerritt.edu/academic_affairs/irb.

The principal investigator starts the review process by filing an application *(Protocol Approval Form)* along with supporting information such as consent documents and fliers for recruiting subjects. There should be no instances of N/A in answer to the questions on this form; each question is applicable and should be answered, even if with a simple negative statement.

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 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). Expedited review does not mean that the review will be “faster” than full IRB review. 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.

Please **type** the Protocol Approval Form. This form should be used if:

- you are a student, faculty, or staff of Samuel Merritt University
- you are requesting Exempt, Expedited, or Full Review
- you are submitting for first-time review, renewal of an existing proposal, or modification to an approved IRB proposal.

1. If submitting for **EXEMPT REVIEW**, complete questions 1-25. You can submit **at any time one original and one copy** of the Protocol Approval Form and text of the proposal in appropriate protocol format to Ms. Jamie Hirota, IRB Administrator, SMUIRB Office, 450 30th Street, Suite 2718, Oakland, CA 94609. Your request for exempt status will be reviewed by the chair of the SMUIRB.

2. If submitting for **EXPEDITED REVIEW**, complete questions 1-25. You can submit **at any time one original and two (2) copies** of the Protocol Approval Form and text of the proposal in appropriate protocol format to Jamie Hirota, IRB Administrator, SMUIRB Office,

Room 2718, 450 30th Street, Oakland, CA 94609. Your request for expedited status will be reviewed by the chair of the SMUIRB and if eligible, will be reviewed by two members of the SMUIRB.

3. If requesting **FULL REVIEW**, complete questions 1-6 and then proceed to question 11. You must submit by the **first working day of each month for review within that month, one (1) original and seven (7) copies** of the Protocol Approval Form and text of the proposal in appropriate protocol format, to Jamie Hirota, IRB Administrator, SMUIRB Office, Room 2718, 450 30th Street, Oakland, CA 94609. Your proposal must be delivered to the SMUIRB Office no later than the first working day of the month. Please do not use interoffice mail as there is no guarantee your proposal will be delivered by the deadline; proposals received after the first working day of the month will be held over for review the following month. **Students:** Protocols left with research advisors or department chairs are not considered delivered to the SMUIRB.

4. The text of the proposal should be **typed** using a 12 point font. Number all pages. The text of the proposal should be no more than 10 pages, double-spaced, one-inch margins. This page limit does not include references or appendices. To minimize the use of paper, the proposal can be copied two-sided. If the procedures for data collection (Category C in the Protocol Format) are particularly lengthy or complex, you may attach an additional two (2) pages of text describing the data collection procedures, but you must first obtain permission to do so from the IRB Administrator (510/869-6647). If you have asked and received permission for this purpose, please indicate so in a cover letter to the SMUIRB.

5. **Consent**: Please use the SMUIRB Sample Informed Consent Form, available on the IRB website, to assist you in writing your informed consent. The wording that is not italicized should be incorporated in every consent form. **Students:** Please indicate that you are conducting the study in partial fulfillment for the requirements of your degree.

6. **Appendices**: Please label each appendix referenced in the text of the proposal. You may provide an index of all appendices, but each appendix should be labeled clearly at the top.

7. **Students**: Your IRB proposal must contain the signature of your research advisor or committee chair, indicating your proposal has been read and approved by an individual responsible for your conduct in research. It is the student's responsibility to see that the proposal contains the appropriate signature prior to submitting to the IRB. No student proposal will be reviewed without this signature. If a student proposal is submitted without a faculty signature, the proposal will be returned to the student with a request for faculty signature.

ENCLOSE A <u>SINGLE COPY</u> OF THIS COMPLETED CHECK-OFF LIST WITH YOUR SUBMISSION.

- θ complete the **Protocol Approval Form**.
- θ sign your name
- θ (if you are a student) obtain signature(s) from your faculty research advisor and all committee members.
- θ (if you are a student or faculty) obtain signature(s) from all co-investigators.
- θ (if you are faculty) obtain signature(s) from all committee members.
- θ Is the proposal double spaced?
- θ Are all pages numbered?
- θ include copies of all letters of support from institutions or agencies from which you are requesting access to facilities, subjects, or subject information. **Letters of support MUST be on institutional letterhead and contain: name of study, name of principal investigators, statement that the institution cannot collect fees for services provided as part of the study, and that the institution is liable for injury to the patient while participating in the study.**
- θ include IRB approval from participating institutions that have an IRB or a statement of concurrent IRB submission.
- θ include copies of all letters of support from research consultants.
- θ include copies of all instruments to be used in data collection.
- θ include copies of any project flyers announcing the project to subjects and/or a copy of a recruitment advertisement in any other form e.g., newspaper ad.
- θ include copies of all educational materials to be distributed to subjects in the course of the research project as a part of a planned intervention with a treatment and/or to be given to a control group, or to be given to all participants for ethical or other reasons.
- θ include a copy of the **Informed Consent** form.
- θ include a copy of Experimental Subject's Bill of Rights.
- θ Include a copy of the complete curriculum vitae of the principal investigator and co-investigators if they are **NOT a faculty or student** at Samuel Merritt University.
- θ Include a copy of curriculum vitae of research committee members only they are **NOT faculty** at Samuel Merritt University.
- θ Include copies of the documentation that all members of the research team have completed the IRB certification requirement (NIH or CITI training).

If you have questions about the SMUIRB process, contact Jamie Hirota, IRB Administrator, (510) 869-6647 (jhirota@samuelmerritt.edu) from 8:00 a.m. to 5:00 p.m. Monday through Friday. Jamie's office is in the Peralta Pavilion, 450 30th Street, Second Floor, Room 2718.