Expedited Review	
HSC SOP No:	016
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1. PURPOSE

1.1. In order to be eligible for expedited review, research activities must present no more than minimal risk to human subjects and only involve procedures as described in one or more of the specific categories listed in the regulations at Federal Register Volume 63, No 216.

1.2. For purposes of confirming an exemption determination, projects eligible for exemption may also bereviewed under expedited review procedures. Research for which limited IRB review is a condition of exemption are also eligible for expedited review procedures, so long as the review documents that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data. Exempt determinations are covered in depth under HS SOP *015 Exemption Determination.*

2. DEFINITIONS

2.1. *Minimal risk,* as defined in federal regulations by 45 CFR 46.102 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.

2.2. *Children,* as defined in federal regulations by 45 CFR 46.402 means persons who have not yet attained the legal age for consent to treatment or procedures involved in research, under the applicable law of jurisdiction in which the research is conducted.

2.3. *Prisoner,* as defined in federal regulations by 45 CFR 46.303 means that any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individual sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

3. POLICY and PROCEDURE

3.1. **Applicability**

3.1.1. The activities listed in the regulations at Federal Register Volume 63, No 216 should not be deemed to be of minimal risk simply because they are included on the list. Inclusion on this list means only that the activity is eligible for review through the expedited review process when specific circumstances of the proposed research involve no more than minimal risk of harm to the subjects.

3.1.2. The categories in this list apply regardless of the age of subjects, except as noted.

3.1.3. 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 risk, the expedited review procedures may not be used where identification of the participants and/or their responses would reasonably place

them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing.

3.1.4. The expedited review procedures may not be used for classified research involving human subjects.

3.1.5. The expedited review procedures may not be used for research involving prisoners, unless the prisoner representative of the IRB is one of the designated reviewers and the project qualifies as no greater than minimal risk.

3.1.6. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of whether the research is reviewed by the convened IRB or by expedited review procedures.

3.2. **Expedited Review Categories (Federal Register Volume 63, No 216.)**

(1) 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 (21CFR Part 312) 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 (21 CFR Part812) 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, non-pregnant 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, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50ml 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 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) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base 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 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 subject or an invasion of the subject'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.

(5) 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 human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

(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. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(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 two (2) through eight (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.

3.3. **Authority of the IRB Chair and/or Designee**

3.3.1. Under expedited review procedures, the review may be carried out by the IRB Chair and/or by one or more experienced reviewers designated by the IRB Chair from among the members of the IRB.

3.3.2. In reviewing research via expedited review procedures, the IRB Chair or reviewer may exercise all of the authorities of the IRB, except they may not disapprove of a research application. A research application may only be disapproved after review by the convened IRB. Expedited reviewers may exercise authority as permitted and specified by the IRB Chair.

3.4. **Notification of the IRB**

The IRB staff provide IRB members with a list of new applications, continuing review applications, and amendments approved by expedited review procedures at each convened meeting.

3.5. **Documentation**

When research applications are reviewed by expedited procedures, the IRB records will indicate the permissible category or categories of expedited review, or exemption qualification that applies, documenting that the research is no greater than minimal risk. This documentation occurs in the protocol application and categories of research are specified on the approval notice.

3.6. **Minor Changes in Approved Research**

3.6.1. Minor changes in previously approved research during the period for which approval is authorized may be handled via expedited review procedures. Any revision that presents more than minimal risk of harm to the subjects must be reviewed by the full board at a convened meeting.

3.6.2. Changes that are considered administrative in nature may be reviewed and handled by an IRB staff member who also has been appointed to the IRB as a voting committee member.

a. Personnel changes: Personnel changes, other than changing the Faculty Advisor, may be reviewed and handled administratively.

b. Spelling errors or typos: Spelling errors or typos may be corrected administratively.
c. Other minor changes (e.g., adding a new title, removing collaborators, etc.): An IRB Chair/Designee or IRB staff member who has been appointed as a voting committee member may use the expedited review procedures to review and approve of minor changes in research protocols that were previously approved via expedited and/or full committee review during the period for which approval is authorized.

4. SCOPE

These policies and procedure apply to all exempt and non-exempt human subjects' research.

5. RESPONSIBILITY

The IRB staff are responsible for facilitating the review of expedited applications and pre-reviewing submission to ensure they qualify for expedited review procedures, as well as providing the IRB with a list of protocols that were reviewed via expedited review procedures at convened meetings. IRB staff may consult with the IRB Chair/Designee, Director, as needed, in determining if an application may qualify for expedited review procedures.

The IRB Chair/Designee and/or assigned IRB member is responsible for the review and approval of all applications eligible for expedited review. An IRB staff member who is also appointed to the IRB as voting member may be responsible for reviewing applications eligible for expedited review in consultation with the IRB Chair/Designee.

IRB members may be consulted and/or conduct reviews as needed or requested by the IRB Chair or assigned IRB member based on their specific expertise. Ad hoc consultants may also be asked to review the research, if needed, if the research activities involve issues that necessitate the additional consultation of someone with relevant expertise outside the realm of the IRB members. An ad hoc consultant does not have the authority to vote or take action on a research application.

6. EXPEDITED REVIEW PROCESS OVERVIEW

The IRB staff will coordinate the review process and perform a preliminary check of applications (new, amendments, or renewals) that appear to qualify for expedited review. If additional information or clarification is necessary, the responsible staff member initiates correspondence, which may include requests for revisions, with the investigator. After the investigator responds to the requested information, the staff member verifies that all items have been addressed and the application is complete.

6.1. The IRB staff member will set-up the application for review at the next regularly scheduled expedited review meeting.

6.2. Amendments that are deemed administrative in nature, for example personnel changes, or changing the wording to an interview question, checking the signature line on the consent form may be reviewed and approved by administrative procedures that need not be set-up for the regularly scheduled expedited review meeting. The IRB staff member approving these changes must also be a voting member of the IRB.

6.3. During the expedited review meeting, the IRB Chair/Designee and IRB member reviewer will review the application.

6.4. The expedited review process may:

- Approve the protocol;
- Require modifications to secure approval;
- Route the protocol to Full Board review if it is discovered the application does present greater than minimal risk to the subjects

The expedited review process may not:

- Result in withholding approval

6.5. If revisions are requested following the scheduled expedited review, the IRB staff member will follow-up with the investigator in writing. The IRB staff member may review the revised protocol once the investigator has submitted their revisions. The staff member, provided they have been appointed as a voting member of the IRB, may verify that all items have been completed, and/or consult with the IRB Chair/Designee if needed, and approve the protocol.

6.6. If there are no revisions, concerns, or clarifications, the IRB Chair/Designee, IRB staff member who is also a voting member of the IRB, and/or IRB member will approve the research.

6.7. After the application has been approved, all approved documents, including informed consent, parental permission, assent, measures, and approved protocol will be made available to the investigator, along with the protocol approval letter.

References:

45 CFR 46 Regulations

Federal Register Volume 63, No 216

UC Berkeley Policies and Procedures

OHRP Guidance on the Use of Expedited Review Procedures

The Belmont Report