

Title: IRB Review of Expedited Research
Standard Operating Policy: #9
Department: Human Research Protection Program/Institutional Review Board
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Subject: IRB Review of Human Subjects Research—Expedited

Policy:

It is the policy of the LLNL Institutional Review Board (IRB) that all human subjects research activities under its jurisdiction be reviewed to determine whether the research meets one or more of the expedited categories described in the federal regulations.

Procedures:

Federal regulations allow the IRB to review certain human subjects research on an expedited basis if the study meets specified criteria. All expedited studies are reviewed by the IRB at least once per year. Additionally, the standard requirements for informed consent (or its waiver or alteration) apply to all IRB approvals regardless of the type of review, expedited or full committee, utilized by the IRB.

At LLNL an expedited review consists of a review by two (2) members of the IRB. In reviewing the research, the reviewer may exercise all of the authorities of the full committee except that the reviewer may not disapprove the research. Disapproval is only determined by the full IRB Committee. Additionally, the reviewer may refer the study to the full committee for review.

The IRB may use an expedited procedure to conduct initial review of research provided all research activities do not fall under any of the general restrictions, present no more than minimal risk to human subjects, and that expedited procedures not be used when the research is classified, or when identification of the participants or their responses would reasonably place them at social or legal risk.

The IRB may review research through the expedited review procedures in the following research categories as designated by the federal regulations:

- 1. Clinical studies of drugs and medical devices.** The LLNL IRB will not review clinical studies of drugs under the expedited process and will only allow studies involving devices to be reviewed under the expedited process if:

- a. An Investigational Device Exemption (IDE) is not required by the FDA, and
- b. The device will not come into direct contact with a living human body.

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 two 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, 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/kg in an 8-week period, and collection may not occur more frequently than two times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:

- 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; and/or
- 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 include:
 - 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 nonresearch purposes (e.g., medical treatment or diagnosis).** **Note:** some research in this category may be exempt from HHS regulations (see *Standard Operating Procedure #8, IRB Review of Human Subjects Research—Exempt*). 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 HHS regulations (see *Standard Operating Procedure #8, IRB Review of Human Subjects Research—Exempt*). This listing refers only to research that is not exempt.

8. **Continuing review of research previously approved by the fully convened IRB as follows:**

- a. Where the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and the research remains active only for long-term follow-up of subjects.
- b. Where no subjects have been enrolled and no additional risks have been identified.
- 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.

Submission of Application Materials to the IRB

Investigators wishing to have a new study reviewed under the expedited procedure must submit their study to the Human Research Protection Office using the Expedited Review application form. The investigator will indicate on the application form which categories of expedited review he/she believes the study qualifies under. Research materials submitted must conform to IRB requirements and include sufficient detail for the reviewer to determine whether the study qualifies for review and approval under the expedited categories. There are no deadlines for submission of Expedited Review application forms. Investigators applying for new/initial Expedited Review must submit:

- Completed Expedited Review application form.
- Proposed Informed Consent document.
- Copies of the Sponsor's Company Protocol, if sponsored by a for-profit entity.
- Copies of the research proposal, if sponsored by a federal agency.
- If research is being conducted in collaboration with an international entity, evidence of IRB approval from the entity.
- Surveys, questionnaires, scripts, diaries, and any other assessment instruments, if applicable.
- For studies involving minors in school settings, approval letter from the School Principal or School District Office.
- Advertisements, flyers, electronic notices used to recruit subjects.
- Human Stem Cell Research Supplement Form, if applicable.
- Completion of required educational training of all members of the research team, which will be verified by the Human Research Protection Office through its online tutorial tracking system.

- Financial Disclosure Statement.

IRB Review

Two (2) or more experienced reviewers designated by the IRB Chair and IRB Manager will review and approve research, which meets expedited criteria. An experienced IRB member is a voting member or alternate voting member who has served on an IRB for at least one year, has received training relative to the expedited review categories, and possesses the scientific expertise needed to review the proposed research. The reviewer may request an additional reviewer or refer the research to the full IRB Committee for further determination. The reviewer may also request review of the research by an expert consultant for issues which require expertise beyond, or in addition to, that available on the Committee. Should the IRB reviewer(s) require clarification or revisions to the proposed research; this information will be communicated to the Investigator typically within one to two days after review. Instructions for resubmission to the IRB will be indicated in the IRB correspondence. In reviewing the research, the reviewer may exercise all of the authorities of the full committee *except that the reviewer may not disapprove the research. Disapproval is only determined by the full IRB Committee.* Additionally, the reviewer may refer the study to the full committee for review. Investigators applying for continuing review (renewal) through the expedited review process must adhere to the IRB policy on continuing review.

Information obtained during the review of a modification, adverse event, sponsor notification, or other pertinent information may possibly disqualify the study from being approved under an expedited status. In such cases, the study will be forwarded to the full IRB Committee for determination.

As required by federal regulations, the full IRB Committees are advised of research studies that have been approved under the expedited review procedure. Identification of all such studies is documented in the agendas provided to the full IRB Committees. This documentation includes:

- Name of Principal Investigator
- IRB Reviewer
- Study Approval Date
- Study Expiration Date
- Expedited Category/Categories of Approval
- Principal Investigator's Department
- Title of the Study

References:

45 CFR 46.110

21 CFR 56.110

OHRP Guidance on Expedited Review