Title: IRB Review of Expedited Research
Standard Operating Policy: #9
Department: Human Research Protection Program/Institutional Review Board
Original Publication Date: March 22, 2010
Revision Date: September 2017

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 typically 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, in consultation with the Chari and Program Manager, 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:

An expedited review procedure consists of a review of research involving human subjects by the IRB Chair or by one or more experienced reviewers designated by the Chair from among members of the IRB in accordance with requirements set forth in 45 CFR 46.110. Expedited review may be conducted when the research is found to involve no more that minimal risk.

These criteria apply when determining whether or not a protocol qualifies for expedited review.

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 IRB Office using the appropriate IRB forms. 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 application forms. Investigators applying for new/initial expedited review must submit:

- Completed 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.
- Completion of required educational training of all members of the research team, which will be verified by the IRB Office.
- Financial Disclosure Statement.

IRB Review

Two (2) or more experienced reviewers designated by the IRB Chair and IRB Program 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 upon consultation with the IRB Chair and Program Manager, refer the research to the full IRB committee for further determination. 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.* 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 committee is 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 committee. This documentation includes:

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

References:
45 CFR 46.110
21 CFR 56.110
OHRP Guidance on Expedited Review