

## Overview

Lawrence Livermore National Laboratory (LLNL) and the LLNL IRB are responsible for the essential records that are prepared and maintained by the IRB and for retention of such records in accordance with federal regulations and this Standard Operating Procedure (SOP).

## Procedure

### A. IRB Records

1. The LLNL IRB will prepare and maintain documentation of IRB activities and regulatory requirements to include:
  - a. Applications
    - i. Copies of all research proposals reviewed;
    - ii. Scientific evaluations, if any, that were conducted for review of the research proposals;
    - iii. Approved consent document(s);
    - iv. Statements of significant new findings that developed during the course of research in which may relate to the subject's willingness to continue participation that were provided to subjects as required by 45 CFR 46.116 and 21 CFR 56.109
    - v. IRB review whether conducted by expedited review or the convened IRB (*e.g.*, in notes, correspondence, IRB reviewer form), including actions taken by reviewer or Board, approval and expiration dates), determinations (*e.g.*, waiver of informed consent, waiver of documentation of informed consent, regulatory subpart-specific determinations), restrictions (*e.g.*, suspensions, contingencies), and reviewers;
    - vi. Recruitment and advertisement materials;
    - vii. For clinical trials: investigator brochure, drug package inserts and device manuals (if applicable)
  - b. Amendments or modifications to protocols
  - c. Reportable events, such as unanticipated problems involving risks to subjects
  - d. Data and Safety Monitoring reports (if applicable)
  - e. Noncompliance findings / reports and documentation of outcomes
  - f. Reporting to federal, regulatory agencies and any interactions with agencies regarding compliance matters
  - g. Records of annual and continuing review activities (including progress reports)
  - h. Copies of all correspondence between the IRB and the PIs including approval letters and exemption determinations

- i. IRB Membership (including IRB Rosters)
- j. Changes in IRB membership that were reporting to the OHRP;
- k. Versions of written SOPs and IRB Policies

## **B. IRB Record Retention and Storage Applications and Protocols**

The IRB records will be retained for at least three (3) years *after completion* of the research.

1. Paper records for the previous three years are maintained and stored in the IRB Program Manager's office at LLNL.
2. Electronic files and correspondence are on the LLNL secure server

## **C. Minutes of Convened IRB Meetings**

Approved meeting minutes are stored electronically on the LLNL secure server and a paper copy is kept in a binder in the IRB Program Manager's office.

Paper copies of meeting minutes are retained until all studies that were reviewed at that meeting have been completed for at least three years.

## **REFERENCES:**

45 CFR 46.103(b) (3); 46.115(a) (2) & (b); 46.116(b) (5)  
21 CFR 56.115 (a) (2); 56.115 (b)

## Document Review History

Revision Number	Date	Author	Summary of Changes
01	November 2019	IRB Office	New
02	October 2020	Ann-Marie Dake	Revisions and updates