



Policy & Procedure Reportable Events	Effective Date	2/1/2026
	Revision Date	January 2026
	Revision No.	4.0

I. PURPOSE & SCOPE

This guidance establishes how reportable events of any kind that occur during human subjects research (HSR) shall be documented for, and reviewed by, the Human Subjects Committee (HSC) of the Lawrence Berkeley National Laboratory (Berkeley Lab). This reporting is a critical element of oversight during the conduct of HSR in order to meet federal regulatory requirements. This policy applies to all HSR conducted under the oversight of the HSC as the Reviewing IRB, as well as other HSR conducted by an employee or collaborator covered under the Berkeley Lab Federalwide Assurance or conducted with Berkeley Lab funding.

II. REVISION HISTORY

Date	Version No.	Change	Reference Section(s)
01/31/10	1.0	New Procedure Drafted	Not Applicable
9/17/12	1.1	Reformat, terminology update	All
12/2018	2.0	Updated for consistency with the Revised Common Rule	All
06/2023	3.0	Updated throughout	All
01/2026	4.0	Updated to meet DOE Order 443.1C.chg1 and increase clarity.	All

III. POLICY

The policy of Berkeley Lab is to ensure that the HSC is notified promptly of all reportable events occurring during the conduct of or associated with human subjects research performed by or funded through the institution.

A. INVESTIGATOR REPORTING

In order to meet external reporting requirements, as well as to ensure the timely resolution of any reportable events, the following reporting timelines are required of all study team staff upon learning of a reportable event.

***NOTE:** Direct communication may be facilitated through the Protocol Lead Investigator (PLI) or Co-PLI, however, timelines must be maintained when those team members are not available, and so every study team member must be prepared to complete reporting.*

- 1. Urgent Reportable Events.** Immediate reporting to the HSC by phone or email as soon as possible under the circumstances, is required upon learning of the following events;



- a) Any suspected or confirmed incidents involving the loss of control, unauthorized disclosure, or unauthorized access of Personally Identifiable Information (PII) in printed or electronic form.
 - b) Any serious adverse event
 - c) Any significant adverse events, unanticipated problems, or complaints about the research either from participants or someone else;
 - d) Any suspension or termination of IRB approval by an IRB of record other than the HSC.
 - e) Any known or potential incident of noncompliance with the requirements of the applicable regulations, or the requirements or determinations of the HSC.
- 2. FDA-Regulated Reportable Events.** Prompt reporting to the IRB as required by 21 CFR 56.108, 21 CFR 312.66, or 21 CFR 812.150(a)(1), as applicable. Including:
- a) Unanticipated Problems involving risks to human subjects or others, including adverse events.
 - b) For IDE studies, additional reports of unanticipated adverse device effects (UADE) are required to the sponsor and the reviewing IRB as soon as possible, but in no event later than 10 working days after the investigator first learns of the effect.
- 3. Non-Urgent Reportable Events and Minor Deviations.** Events that do not meet the criteria for 'Immediate' reporting, above, but represent a departure from the approved protocol or a minor adverse event must be reported to the HSC. These scenarios may be reported in a reasonable timeframe based on the necessary investigation to determine the severity and corrective actions. In most cases, reporting is expected within 5 business days.
- a) **Minor/Expected Issues:** Potential adverse events that are already identified in the protocol and do not escalate in severity, or that are only possible correlated to the research.
 - (1) Example: A subject in a study feels ill during the research activity and cannot complete the visit. While their illness may not be associated with the research, it should still be documented for potential follow-up.
 - (2) Example: A subject in a demonstration study is inconvenienced by the contractors installing equipment, which was noted as a possibility in the risk section of the consent. However, the inconvenience requires more follow-up, time, and/or action from the study team than is considered “usual.”
 - b) **Minor Protocol Deviations (Non-Compliance):** Incidents where the protocol wasn't followed perfectly, but the subject was never at risk and the data integrity remains intact. *NOTE: Protocol deviations **must** be reported whether they are intentional or accidental.*



- (1) Example: A change in study personnel where the new staff member has completed all training but hasn't been officially added to the "Staff List" in the IRB system yet.
 - (2) Example: A survey was administered in a quiet breakroom instead of the designated "private office" specified in the protocol, but no PII was overheard.
 - (3) Example: An investigator used a version of the recruitment flyer that had the wrong phone number, which was corrected immediately.
- c) Equipment Failures:** Small issues with research equipment that lead to gaps in the data or require follow-up from the study team but do not result in increased risk to the participants.
- (1) Example: An energy use monitor failed to record data for 2 days during a 2-week cycle. The subjects were unaffected, but the data point is lost.
 - (2) Example: A software glitch caused a survey to skip a non-critical demographic question.

B. INSTITUTIONAL REPORTING

The Berkeley Lab Human Subjects Protection Program (HSPP) is required to notify external regulatory bodies with oversight over the study.

1. Notifications to the FDA are required for all FDA-regulated human subjects research according to 21 CFR 56.108(b), for the following items:
 - a) Any unanticipated problems involving risk to human subjects and others;
 - b) Any instance of serious or continuing noncompliance with the regulations or the requirements or determinations of the IRB; and
 - c) Any suspension or termination of IRB approval.
2. Notifications to the Office of Human Research Protection (OHRP), and to the LBNL Office of the Chief Financial Officer for reporting to the funding agency, are required when the event occurs in a non-exempt research activity funded by a federal Common Rule agency and it includes:
 - a) any unanticipated problems involving risks to subjects or others
 - b) any serious or continuing noncompliance with 45 CFR part 46 or the requirements or determinations of the IRB; and
 - c) any suspension or termination of IRB approval.
3. Notifications to the DOE HSPP managers of the following items to comply with the following DOE Order 443.1C.chg1 requirements:
 - a) Immediate Reporting (upon learning of the event)**
 - (1) Serious Adverse Events: Any research-related event that is fatal, life-threatening, results in hospitalization, or causes significant disability.
 - (2) Data Breaches (PII): Any suspected or confirmed breach of Personally Identifiable Information (PII). PII breaches must also be reported immediately to the Integrated Joint Cybersecurity Coordination Center (iJC3).



- (3) Leadership Changes: Notification of the appointment of a new Institutional Official (IO), IRB Chair, or IRB Vice-Chair for the site.

b) Two-Business-Day Reporting

- (1) Significant Adverse Events: Adverse events that substantively impact the rights, safety, or welfare of subjects but do not meet the "Serious" definition.
- (2) Unanticipated Problems (UPs): Any incident or outcome that was unexpected, related to the research, and suggests increased risk.
- (3) Subject Complaints: Any complaints indicating an unanticipated risk or that the research is not being conducted as approved.
- (4) IRB Status Changes: Any suspension or termination of IRB approval for a project.
- (5) Noncompliance: Known or potential incidents of noncompliance with the DOE Order, the Common Rule (10 CFR 745), or 45 CFR 46.

c) Notification Prior to Initiation of any new HSR involving:

- (1) an institution without an established Institutional Review Board (IRB);
- (2) a foreign country;
- (3) the potential for significant controversy (e.g., negative press or reaction from stakeholder or oversight groups);
- (4) research subjects in a protected class (including the populations identified in Subparts B, C, and D of 45 CFR Part 46), as well as others such as individuals with impaired decision-making capability and DOE/NNSA Federal or DOE/NNSA contractor employees as human subjects, who may be more vulnerable to coercion and undue influence to participate, that is outside of the reviewing IRB’s typical range/scope; or
- (5) generation or use of classified information.

IV. ROLES & RESPONSIBILITIES

Role	Responsibility
All HSR Personnel	Must comply with this guidance and report all relevant events according to the specified timelines and procedures.
Protocol Lead Investigators (PLI) & Co-PLIs	Retain ultimate responsibility for ensuring all reporting requirements are met throughout the duration of the human subjects research.
HSC Chair or Designee	Responsible for complying with this guidance and conducting the initial review of all submitted adverse and reportable event reports.



Role	Responsibility
Berkeley Lab HARC Office	Responsible for facilitating all required communications, documentation, and administrative support for the reporting process as the staff supporting the HSPP.
Full Human Subjects Committee (HSC)	Responsible for reviewing reports of adverse, unanticipated, and/or reportable events that are referred by the Chair or designee for full committee oversight.

V. PROCEDURES

A. Event Reporting

1. The PLI, Co-PLI, or Study Coordinator shall submit Reports through the following methods:
 - a) All events requiring immediate reporting should be communicated by phone or email to the HARC Office to properly address the issue in a timely manner.
 - b) All reportable events, including those initially reported by phone or email, must be logged through completion of the HSC Reportable Event Submission Form. This form allows for triaging by HARC staff and the HSC Chair to establish next steps, and serves as long-term documentation. For completeness, this record should include uploads of the reports generated through email or other means.
 - c) In addition, a summary of all reportable events associated with the study must be reported to the HSC at the time of the continuing review or annual check-in, as applicable.
2. In the Report, the PLI will include the study team’s assessment of causality (related or not related to the study); a description of the actual event; and either a justification why no changes to the protocol or consent form are needed or a description of proposed modifications to the protocol or consent form.

B. Review of the Reported Event

1. Inquiry

Upon receiving a report of an adverse, unanticipated, or otherwise reportable event, initial data collection will be conducted by the Human and Animal Regulatory Committees (HARC) Office. This process may include gathering documentation from study records and conducting preliminary conversations with the Protocol Lead Investigator (PLI) and responsible research team.

2. Assessment

Initial data is reviewed by the HSPP Leadership Team, consisting of the HSC Chair, Vice Chair, and the HARC Program Manager. This team will assess:



- a) Whether immediate actions, such as administrative suspension to protect participants from imminent harm, are required.
- b) The appropriate level of institutional notification, including informing the Institutional Official (IO) and/or the DOE Site Office.
- c) Whether the event meets criteria for external reporting to the Department of Energy (DOE), FDA, or OHRP, as established in the Policy section of this document.

3. Evaluation

If the initial assessment confirms the incident meets the definition of a reportable event, the Leadership Team will evaluate the findings to:

- a) Request further investigation or additional clarifications from the research team if contributing factors remain unclear.
- b) Determine recommended corrective actions to prevent recurrence.
- c) Decide on the necessary oversight path:
 - (1) Administrative Review: Corrective actions for minor events are communicated directly to the PI, with a summary provided to the HSC during the next convened meeting.
 - (2) Committee Elevation: The event is referred to the Full Human Subjects Committee if it is a Full IRB Review study, or regardless of the study's original review category, in the following circumstances:
 - (a) The HSPP Leadership Team cannot reach a consensus on required actions, or any member requests full board review.
 - (b) The study is FDA-regulated.
 - (c) The event appears to form part of a pattern of continuing or repeated non-compliance.
 - (d) A reviewer or member of the Leadership team believes the study should be suspended or terminated. *NOTE: If participants or others are at immediate risk of harm and there is insufficient time to wait for review by the convened HSC, the protocol may be suspended in the HARP system with a notification to the investigator to halt all work until the review can be completed.*

4. Corrective Action Plans

- a) If elevated for discussion by the committee, the convened quorum will review the investigation findings and the leadership recommended corrective action plan, if any. The HSC may, by a majority vote of the convened quorum, impose required corrective actions, such as:



- (1) Requiring additional training for study team members.
- (2) Providing updated information to current or former research subjects.
- (3) Requiring modifications to the protocol or consent documents.
- (4) Shortening the protocol approval duration or increasing the frequency of continuing review.
- (5) Suspending or terminating study approval.

b) For Exempt or Expedited protocols not otherwise referred to the full committee, a member of the HSC will perform the review, and the final corrective action plan will be determined in consensus with the HSPP Leadership Team.

C. Reporting outside the HSC

- 1. All reporting timelines established in the Policy section 3.B. must be met, as determined by the categorization of the Reportable Event. The HSPP shall report the occurrence via email or phone, including any corrective actions taken, to the Department of Energy Human Subjects Protection Program manager, with a cc to the LBNL Site Office.
- 2. Reporting to the FDA must be performed promptly via email as indicated on their website, which indicates reports of suspensions or terminations of IRB approval should include:
 - a) The IND or IDE number,
 - b) the full name of the research protocol,
 - c) the name(s) of the clinical investigators, and
 - d) the reason(s) for the suspension or termination.
- 3. Reporting to OHRP must be performed promptly via their online incident report form.
- 4. For research activities funded outside of the federal Common Rule agencies, the PI will be required to self-report to their program managers as appropriate based on the specific language of the funding contract.

VI. AUTHORITIES AND REFERENCES

Title	Web Link (as of 01/2026)	Description	Type
10 CFR Part 745	https://www.ecfr.gov/current/title-10/chapter-III/part-745	The Common Rule regulations - Dept of Energy version	Regulatory Authorities
DOE Order 443.1C.chg.1 - Protection of Human Research Subjects (or current version)	https://www.directives.doe.gov/directives-documents/400-series/0443.1-border-c-chg1-ltdchg	Dept of Energy Order applicable to research performed by or through LBNL. Contractor Requirements Document is incorporated into Contract 31.	Regulatory Authorities
45 CFR 46	https://www.ecfr.gov/current/title-45/part-46	The Common Rule regulations - HHS	Regulatory Authorities



21 CFR Parts 50 & 56	https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-50 https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56	Food & Drug Administration (FDA) regulations governing human subjects research and IRB requirements for FDA-regulated products.	Regulatory Authorities
UC-DOE Prime Contract	https://www.ucop.edu/laboratory-management/contracts/lbnl/index.html	UC-DOE Prime Contract for the management and operation of Lawrence Berkeley National Laboratory (LBNL).	Source Requirements
The Belmont Report	https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html	Foundational document outlining core ethical principles and guidelines for research involving human subjects.	Source Requirements
UCOP Policy for Protection of Human Subjects in Research	https://policy.ucop.edu/doc/2500499/ProtectHumanSubject	Governing policy for the University of California system, applicable to research performed by LBNL.	Source Requirements
Berkeley Lab's Federalwide Assurance for Protection of Human Subjects	https://commons.lbl.gov/download/attachments/93095490/FWA%208-16-2021.pdf?version=1&modificationDate=1629153435063&api=v2	Current version of FWA on file with the Office for Human Research Protections (OHRP)	Source Requirements
PUB-3000 Chapter 22 03.02.002.001	https://ehs.lbl.gov/resource/esh-manual-pub-3000/ch22/	Overview of standards for Research with Human and Animal Subjects	Source Requirements
Human Subjects Committee Charter	https://commons.lbl.gov/download/attachments/93095490/LBNL%20HSC%20Charter%202021%20FINAL.pdf?version=1&modificationDate=1633976726304&api=v2	Charter establishing HSC composition and high level processes.	Implementing Document
OHRP Guidance - Reviewing Unanticipated Problems	https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html#AA	Formal regulatory guidance from OHRP	Reference Material
OHRP Guidance - Reporting Incidents	https://www.hhs.gov/ohrp/compliance-and-reporting/guidance-on-reporting-incident/index.html	Formal regulatory guidance from OHRP	Reference Material
FDA Guidance - What is a Serious Adverse Event	https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event	Formal regulatory guidance from FDA	Reference Material
HSC Website	https://commons.lbl.gov/display/harc/Human+Subjects+Committee	Website for the Human Subjects Committee that holds extensive resources.	Reference Material

VII. Appendix 1

HSC Reportable Event Requirements

Significant Adverse Events

Any unfavorable occurrence associated with research participation, and substantively impacting the participant(s)

Unanticipated Problems

- 1) Unexpected
- 2) Possibly Related to the research
- 3) Likely to increase risk to subjects or others

Complaints about the Research

Regardless of whether from participants or bystanders, and whether it was resolved

Noncompliance

Ex. protocol deviations, failure to report, conducting Human Subjects Research without approvals

Report to the HARC Office
immediately upon learning of the event
Call: 510-486-6005
Email: HARC@lbl.gov

Data Breaches and/or Loss of PII

DOE Order 206.1 - *Immediate* Reporting to DOE-Cyber Incident Response Capability
 DOE Order 443.1C - *Immediate* Reporting to HARC/DOE HSPP

APPLICABILITY

All Study Team Members Share Responsibility for Reporting, not only the PI or LBNL employees

Failure to meet these requirements will result in noncompliance

If you're unsure,
****REPORT ANYWAY****
 HARC can help