UCLA Research Administration
Human Research Protection Program

Policy and Guidance: Use of Human Subjects Research Data and/or Biospecimens Collected Without Prior IRB Approval

Version date: November 30, 2023
Policy approved by Human Research Policy Board: November 30, 2023

Overview

Federal regulations and UCLA policy[1] require IRB approval prior to the conduct of all non-exempt research involving human participants. Federal regulations and UCLA policy do not allow the IRB to grant retroactive approval for already-conducted human subjects research activities. The UCLA IRB will consider proposals for future research use of data and/or biospecimens that were collected without prior IRB approval or in a manner not consistent with the IRB-approved protocol when appropriate.

This policy and guidance:

- defines the circumstances in which research activities are considered to have been conducted without prior UCLA IRB approval;
- outlines the investigator's responsibilities for identifying and reporting such circumstances to the UCLA OHRPP/IRB; and
- details the UCLA OHRPP/IRB review considerations and potential outcomes.

Applicability

This policy applies to nonexempt human subjects research activities in which UCLA is engaged or for which the UCLA IRB is the IRB of record. If the research was reviewed by an External IRB (as documented in a formal agreement with UCLA), the investigator should follow the policies and procedures of the External IRB.

Definitions

"**Conducting research**" includes recruitment, consent, and data or biospecimen collection and analysis.

"**IRB review**" for UCLA researchers may be conducted by one of the UCLA IRBs or by an External IRB that has executed a reliance agreement to conduct the review on behalf of UCLA.

[1] UCLA Policy 991 stipulates, "All faculty and staff who are conducting studies involving Human Subjects within the course and scope of their duties, as well as UCLA students who are conducting studies involving Human Subjects within the course of their studies, regardless of the source of the funding, or even in certain cases in which no funds are involved, are required without exception to have prior approval from the IRB before Research is initiated."

Nonexempt Human Subjects Research are activities that qualify as human subjects research under the Department of Health and Human Services 2018 Revised Common Rule (45 CFR 46) and do not qualify for certification of exemption under one or more of the exemption categories (45 CFR 46.104) in the Common Rule.

Research activities conducted without IRB approval may include any of the following:

- **Not obtaining IRB approval** prior to initiating human subjects research or major changes to approved human subjects research.
- **Initiating study recruitment prior to IRB approval.**
- **Using unapproved consent documents or processes,** including not using the approved processes and documents, or not obtaining informed consent when the IRB did not approve applicable waivers of informed consent.
- **Over-enrolling participants.** IRB review of reports of over-enrollment will take into consideration the study design, type of research (behavioral or clinical) as well as the risk level of research.
- **Continuing research procedures after expiration of IRB approval.** Applies only to studies where the IRB has determined that continuing review is required.
- **Continuing research procedures after suspension or termination of IRB approval.**

Investigator Responsibilities

1. Investigators are responsible for ensuring that all human subjects research receives IRB review and approval prior to commencement. Any investigator who discovers they have conducted research involving human subjects without prior IRB approval must report their project promptly to the IRB/OHRPP.
2. Investigators should also contact their faculty advisor if they are a student researcher, or notify their department chair if they are a faculty member.
3. The investigator must cease all affected activities involving human subjects.
4. The investigator must submit a Post Approval Report (PAR) to the UCLA IRB. The report should describe the unapproved activities, circumstances, and any proposed corrective and preventive actions.

OHRPP initiation of Post Approval Report. If the unapproved activities have been identified by the UCLA OHRPP or by persons other than the investigator/study team, the OHRPP may elect to initiate a Post Approval Report on behalf of the investigator.

UCLA OHRPP/IRB Responsibilities and Review Outcomes

The UCLA OHRPP/IRB will assess the post approval report and consider the following:

1. **Immediate action**. Is there a need for immediate action (e.g., participant safety, sensitive information) or coordination with other institutions or UCLA offices?

2. **IRB approval requirement**. Does the reported research activity involve human subjects and was IRB approval required?

3. **IRB review of the PAR**. When considering the below issues, the IRB review of the PAR will culminate in one of the Committee Action Options. Review may be completed by the convened Board or by the IRB Chair/designee.

4. **Corrective and preventative action plan (CAPA)**. The IRB may require a CAPA plan to address or prevent the consequences of the already-completed research activities and the conduct of future research activities.

5. **HIPAA applicability.** The IRB will assess whether HIPAA research authorizations or waivers of HIPAA research authorization would be applicable to the collection or proposed future use of the data/biospecimens.

6. **Applicability of other laws or approvals.** The IRB will assess whether additional laws (e.g. California Information Practices Act, FERPA) or approvals (e.g., approvals or permissions from non-UCLA sites or collaborators) would be applicable to the collection or proposed future use of the data/biospecimens.

7. **Unanticipated Problems (UAP) and Noncompliance**. The UCLA IRB will use the Post Approval Report checklists to make applicable regulatory assessments.

8. **Use of data/biospecimens.** Federal regulations do not state how data/biospecimens collected without IRB approval may be used. On November 30, 2023, the UCLA Human Research Policy Board (HRPB) determined that:

    a. The UCLA IRB has the authority to review UCLA researcher proposals for future research use of data and/or biospecimens that were collected without prior IRB approval or in a manner not consistent with the IRB-approved protocol.

    b. Such UCLA IRB review should be consistent with March 29, 2021 SACHRP recommendations. These state in part, *"The use of research data should only be restricted when there are substantial violations of the Belmont principles or other ethical standards. Minor infringements of ethical principles should not generally lead to restrictions on data use absent unique compelling facts."*

    c. Possible UCLA IRB determinations may include:
        - Data /biospecimens can be used without further consent of participants.
        - Data/biospecimens may be used from those participants from whom the researcher obtains prospective consent for the planned future research analyses.

- The request may be referred to the Institutional Official and/or Human Research Policy Board for additional discussion and recommendation in the case of complex or sensitive requests.
- The IRB may request that the Institutional Official, the Vice Chancellor for Research, convene an IRB Executive Committee meeting to discuss the case and make recommendations.

9. **Referral to additional UCLA offices or external organizations.** The IRB may determine that additional UCLA offices or external organizations should be involved in the review of the post approval report and/or requests to use data and/or specimens collected without prior IRB approval. Referral to other offices may include:
    a. Referral to aid in the development and/or review of the investigator's Corrective and preventive action plan (CAPA).
    b. Assessment of effect on institutional compliance requirements.
    c. Request for information from UCLA offices or external organizations that were involved with the data collection.
    d. Referral to University Research Integrity Officer (RIO) if applicable.

10. **Reporting to federal funding agencies and federal regulators**. Federal regulations require UCLA OHRPP to report serious or continuing noncompliance to appropriate federal regulators and/or funding agencies. As described in OHRPP Guidance: IRB Reporting Procedures for Unanticipated Problems Noncompliance Suspension or Termination copies may be distributed to other institutions or other UCLA offices.

11. **Administrative Closure.** If the entire research study was conducted without IRB approval and an electronic IRB application has been submitted, the UCLA OHRPP will administratively withdraw the study after all review activity related to the matter has been concluded.

Regulations and Resources

US Department of Health and Human Services (HHS)
45 CFR 46.108(a)(4)
45 CFR 46.118
Guidance on Reporting Incidents to OHRP (2022)
Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance (2007)

US Food and Drug Administration (FDA)
21 CFR 56.108(b)
21 CFR 56.113

HHS Secretary's Advisory Committee for Human Research Protections (SACHRP)
March 29, 2021 - Letter to the HHS Secretary
Attachment A - IRB Authority to Restrict Use of Data Collected and Developed in Research

University of California, Los Angeles (UCLA) Policy
UCLA Policy 991: Protection of Human Subjects in Research
UCLA Policy 993: Responding to Allegations of Research Misconduct

UCLA OHRPP Guidance and Checklists
IRB Reporting Procedures for UAPs, Noncompliance, Suspension or Termination
IRB Committee Action Options
IRB Member Post Approval Report checklists
Investigator Responsibilities for Research Involving Human Subjects
Noncompliance and Allegations of Noncompliance
Post Approval Reporting
Referral to the IRB Executive Committee
Requirements for IRB Review and Approval
Suspension and Termination of Research