Data Collection without IRB Approval	
HSC SOP No:	020
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1. PURPOSE

1.1. Federal regulations require that research involving human subjects be prospectively reviewed and approved by an IRB. Research that falls under full board review procedures will be subject to continuing review by the IRB. All other research activities will be subject to continuing review based on their degree of risk, as determined by the IRB.

1.2. Data collected for research purposes without prior IRB review and approval may be subject to review and discussion by the IRB at a convened meeting. This document describes the circumstances and processes for which data are considered to have been obtained without prospective IRB review.

2. POLICY and PROCEDURE

2.1. Data obtained for human subjects research activities in which the University of California, Santa Barbara is considered to be engaged is considered to have been collected without IRB approval under the following circumstances:

- With no prior IRB approval
- With no prior letter of determination confirming IRB oversight is not required
- With no informed consent from the subjects or their legally authorized representatives (and when the IRB has not approved a waiver of consent or documentation)
- Using procedures that were not previously described and approved in the IRB-approved consent document (unless it has been determined to be in the best interest of the subjects enrolled in the study to continue in the research in consultation with the IRB Chair/Designee or Research Integrity Director)
- After expiration of the IRB approval
- After suspension or termination of IRB approval

2.2. The IRB cannot grant retroactive approval for use of data that was previously collected without IRB approval. Federal regulations allow for IRB approval only when it is prior to the initiation of the research activities.

2.3. The IRB cannot require the investigator destroy data or prevent the investigator from analyzing or publishing the data collected without prior IRB approval. Federal regulations do not state how data collected without IRB approval may be used.

2.4. **Actions Following Data Collected without IRB Approval**

Any investigator who discovers they have conducted research involving human subjects without prior IRB review and approval or exemption determination, must report their project promptly to the IRB. Investigators should also contact their faculty advisor if they are a student researcher, or notify their department chair if they are a faculty member.

2.4.1. The investigator must immediately cease all activities involving human subjects.

2.4.2. The investigator must submit in writing to the IRB a summary of the project to the IRB and why the appropriate approvals were not initially sought and how they will ensure there are no future recurrences. The summary must include the following information:

a. A description of the project (including the dates and location of activities, the human subjects participant population, examples or copies of the survey materials, interview guides, instruments, etc., that were used to collect data);
b. A description of the consent process;
c. A discussion of how the rights and welfare of the participants were not adversely affected (including whether there were any complaints, concerns, complications, unanticipated outcomes or adverse events associated with the research);
d. If identifiable data were collected, the disposition of these materials;
e. Why the appropriate IRB approvals were not initially sought and how the research team will avoid future occurrences.

2.5. Corrective and Preventative Actions

Depending on the circumstances leading to the lack of approval, the IRB may require any of the following corrective actions, or any other action as appropriate:

- Warning letter: Issue a letter of warning to the investigator.
- Publications and presentations: If the data are intended for publication, the investigator must disclose to the publication editor that the data was previously collected without prior IRB approval.
- Publications and presentations: Data cannot be described as being a part of a UCSB IRB-approved study.
- Halt ongoing activities: If the study is on-going, interactions with the human subjects must cease until the IRB has reviewed and approved all the study procedures.
- Modification: If data was collected under an existing study for which the appropriate procedures were not described, some or all part of the protocol may require modification.
- Recollection of data: Data are collected again, but with IRB approval.
- Notification to participants: In some instances, the IRB may require the investigators to notify all participants of the investigator's lack of compliance with the IRB procedures.
- Reconsent: The participants are provided the opportunity to consent to the use of their data for research purposes, using IRB approved documents.
- Retraining: Require retraining of the investigator and researchers conducting the project.

- Notification to OHRP: If there was any risk of harm to the participants, the IRB will report the incident to OHRP and appropriate officials as required by the Federal Wide Assurance.
- Funding agency notification: If the study is federally funded, then the IRB staff must notify Sponsored Projects to report that the research was conducted without prior IRB approval to determine applicable reporting requirements.
- Suspension and termination: If, after the IRB has intervened to take corrective action and the investigator initiates a second study without IRB approval, procedures for suspension and termination may be applied.
- Recommendation of sanctions on data use: Although the IRB cannot impose sanctions on the use of the data, the IRB may recommend that the Institutional Official, or other appropriate officials (e.g., UC Legal) consider the following actions:
  Require that data not be published or presented
  Require data not be used for a thesis or dissertation
  Require that data be destroyed
  Other actions as appropriate

2.4.3. The IRB staff, after review by the IRB, will send a letter of determination to the investigator detailing any corrective actions.

3. SCOPE

These policies and procedures apply to all research submitted to the IRB or under the jurisdiction of the institution.

4. RESPONSIBILITY

The investigator is responsible for ensuring they obtain IRB approval prior to initiating activities involving human subjects. The investigator is also responsible for notifying the IRB of when a violation occurs and ceasing all activities until the IRB has reviewed a summary of the incident.

The IRB staff, IRB Chair, and/or Research Integrity Director are responsible for receiving and reviewing reports of investigators collecting data without prior IRB approval. The IRB staff will facilitate the initial review of the report and will notify investigators of the IRB decision and any corrective action(s) in writing. The IRB staff, IRB Chair and/or Research Integrity Director are responsible for notifying the Institutional Official, as appropriate.

The IRB is responsible for reviewing reports of noncompliance with this SOP and federal regulations.

5. PROCESS OVERVIEW

The IRB staff, IRB Chair, and/or Research Integrity Director will initially receive the reported data collection without IRB approval. The IRB staff will determine whether an approved protocol was in place during the time period in question. If an approved protocol does not/did not exist, then the IRB will review the summary of information provided to the IRB staff.

5.1. The IRB will make a formal determination as to whether the data collected required IRB approval. The IRB will assess:

- Whether the activity constituted research involving human subjects, as defined by federal regulations;
- Whether the project was eligible for an exempt determination, expedited review procedures, or full board review. This determination will also include the category of exemption or expedited review, if applicable;
- A risk/benefit analysis of the research to the participants and whether the project posed any risks of harm to the subjects and how those risks (if any) were mitigated by the researcher;
- Whether there was any coercion or undue influence to the participants.

5.2. Following review and assessment, the IRB may require corrective actions (as described in 2. 5 above) and issue a letter of determination to the investigator.

5.3. The IRB staff will coordinate with the IRB Chair and/or Research Integrity Director to follow-up on any corrective actions required by the IRB.

References:

45 CFR 46 Regulations

OHRP Investigator Responsibilities FAQs