

Data Collection without IRB Approval	
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1. PURPOSE

- 1.1. Federal regulations require that research involving human subjects has been reviewed and approved by an IRB. Research that falls under expedited or full board review procedures will be subject to continuing review by the IRB.
- 1.2. Data collected without prior IRB review and approval may be subject to review and discussion by the IRB at a convened meeting.

2. POLICY and PROCEDURE

2.1. Data obtained for non-exempt 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 following circumstances:

- With no prior IRB review or 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 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.

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

- Issue a letter of warning to the investigator.

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- 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.
- If the study is on-going, interactions with the human subjects must cease until the IRB has reviewed and approved all the study procedures.
- 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 whether the sponsor is required to be notified.
- In some instances, the IRB may require the investigators to notify all participants of the investigator's lack of compliance with the IRB procedures and solicit permission from the participants to use the data collected.
- Require retraining of the investigator and researchers conducting the project.
- 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. In addition, the Institutional Official may forbid publication of the results from the research study.
- 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.

2.4.4. 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 initiation of 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.

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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 2.4) 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