WESTCLIFF UNIVERSITY
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IRB Standard Operating Procedure

SOP 6	Data Collected Without IRB Approval	Effective Date 1/1/2023

PURPOSE

Federal regulations require that research involving human subjects be prospectively reviewed and approved by an IRB. All research supported by the University will be subject to continuing review by the IRB.

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.

DEFINITIONS

Federal regulations allow for IRB approval only when it is before the initiation of the research activities.

Data obtained for human subjects research is considered to have been *collected without IRB approval* given the following contexts:

- without prior IRB approval(s);
- with no prior letter of determination confirming IRB oversight is not required;
- with no informed consent from the subjects or their legally authorized representatives; given that IRB has not issued 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;
- after expiration of the IRB approval; and/or
- after suspension or termination of IRB approval.

Federal regulations do not state how data collected without IRB approval may be used. Nor can the IRB grant retroactive approval for use of data that was previously collected without IRB approval.

POLICY

General Actions. 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 mentor and/or department dean. Moreover:

- the investigator must immediately halt all data collection and analyses;
- the investigator must file an adverse event report with the IRB and request a meeting regarding the event—including information regarding how:
    - a description of activities (dates, locations, participants, population, instruments, protocols/guides, and all other materials/information used while collecting data);
    - a discussion of the intended consent process and how it protected participants;
    - a discussion of whether there were any adverse effects such as complaints, expressed concerns, complications/damages, and other unanticipated adverse outcomes);
    - the state and location of all materials containing identifiers; and
    - a discussion of why the investigator failed to obtain IRB approval before collecting data and how they intend to avoid future occurrences.

Corrective and Preventative Actions. 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 a part of a University IRB-approved study.
- Halt ongoing activities: If the study is ongoing, 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 is 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.
- CITI Retraining: Require retraining of the investigator and mentor conducting the project.
- 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: The IRB may recommend that the Institutional Official and 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

OHRP and/or FWA Considerations. 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. 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.

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

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

- 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; and
- whether there was any coercion or undue influence on/over the participants.

The IRB reserves the right to expand the scope of inquiry. Afterward, the IRB must share a letter of corrective actions with the investigator, mentor, relevant dean(s), and Institutional Official. The IRB staff will coordinate with the IRB Chair and/or Institutional Official to follow up on any corrective actions required by the IRB.

All documentation must be archived in the regulatory binder.

RESPONSIBILITIES

The investigator is responsible for ensuring they obtain IRB approval before 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 an adverse event report of the incident.

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The IRB staff, IRB Chair, and/or Institutional Official 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 Chair is responsible for notifying the Institutional Official, as appropriate.

The IRB and Institutional Official are responsible for reviewing reports of noncompliance with this SOP.

REGULATIONS

45 CFR 46

CONTACT INFORMATION

Please direct questions or concerns about this policy to:

Contact	Title/Role
	IO
Brett Gordon	IRB Chair

DISCLAIMER

The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as a suitable Institutional Official or IRB Member requests review or exception to this SOP.