UNIVERSITY OF SOUTH ALABAMA

IRB SOP 807
Research Procedures Conducted Without IRB Approval

Purpose

Federal regulations requires research involving human subjects be prospectively reviewed and approved by an Institutional Review Board (IRB). This document defines circumstances where human subject's research is considered to have been conducted without obtaining IRB approval. Data collected without IRB approval may be ineligible for use in a study and subject to review and discussion by the convened IRB at the next regularly scheduled meeting.

Scope

This document applies to human subject's research activities in which the University of South Alabama (USA) is engaged or for which the University's IRB is the IRB of record. If the research was reviewed by an External IRB, the researcher should adhere to the policies and procedures of the External IRB.

Policy

Human subjects research procedures conducted without IRB approval is defined as any of the following:

- **Not obtaining prior approval by the USA IRB**, or by an External IRB that has a formal reliance agreement with USA to conduct the review on behalf of the USA IRB.

- **Not obtaining informed consent** from the subjects or their legally authorized representatives when the IRB had not approved a waiver of consent.

- **Using procedures that were not described in the IRB-approved** consent process or document.

- **Not** using an informed consent form that has been approved by USA IRB or an external IRB.

- **Continuing research procedures after the expiration** of IRB approval.

- **Continuing research procedures after suspension/termination** of IRB approval.

The IRB cannot grant retrospective approval for the use of data collected previously without prior approval of the IRB.

The IRB cannot require researchers to destroy data or prevent them from analyzing or publishing the data collected without approval of the IRB. Federal regulations do not state how data collected without IRB approval may be used.

Procedures

1.0 Actions Following Research Conducted without IRB Approval

A researcher who discovers the conduct of human subject's research without prior IRB review and approval or exemption determination must disclose the activity promptly to the IRB Office. If the researcher is a student-investigator, the faculty advisor must also be informed.

Assessment and review. The researcher may be asked for clarifications or additional information so that the Office of Research Compliance and Assurance in collaboration with the IRB can assess information and make the following determinations:

- **Immediate action**. Is there a need for immediate action (e.g., subject safety; involvement of sensitive subject information) or coordination with other institutions or USA offices?

- **IRB approval requirement**. Was IRB approval required? A formal determination will be made to assess whether the project was eligible for exempt determination, expedited review, or full board review. A risk/benefit overview will be assessed to determine if the project posed any risks of harm and how those risks (if any) where mitigated by the researcher.

- **Noncompliance**. Do the activities and circumstances rise to the level of serious noncompliance? Conducting a non-exempt research study/study activities without prospective IRB approved is always considered to be serious noncompliance.

- **IRB review**. Is IRB review of the reported information or a corrective plan required? If yes, IRB assessment and review is conducted.

2.0 Preventive and Corrective Actions

Depending on the situation leading to the lack of approval, the Office of Research Compliance and Assurance and the IRB may require any of the following actions, or any other action as deemed appropriate. Federal regulations and USA policy do not allow the IRB to grant retroactive approval for already-conducted activities. **Federal regulations** are silent on the issue of how the data/specimens may or may not be used or whether they should be destroyed.

- Issue a letter of warning to the investigator.
- Reporting to federal funding agencies and federal regulators if applicable.
- Publications and presentations: Data cannot be described as part of a USA IRB-approved study. This may have implications for the publications or presentations, as many journals and conferences require IRB review as a condition of publication or presentation of research that involved human subjects.
- Halt ongoing activities: If the study is on-going, interactions with the participants must stop until the IRB has reviewed and approved all the study procedures. An exception in this instance would occur where necessary to eliminate an apparent immediate hazard/harm that would occur to the research subject.
- Modification: If data were collected under an existing study for which the appropriate procedures were not described, some or all 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: Required retraining of the investigator and researchers conducting the project.

The IRB Office, after assessment and review is concluded, will send a letter of determination to the researcher detailing any corrective actions.

Related Materials

45 CFR 46.108(a)(4) and 45 CFR 46.118 (2018 Regulations)
45 CFR 46.103(b)(5) and 45 CFR.118 (Pre-2018 Regulations)
21 CFR 56.113 and 21 CFR 56.108(b)

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