

Monitoring of Ongoing Research	
HSC SOP No:	019
Original Procedure Effective Date:	July 14, 2015
Date Revised:	July 9, 2019, May 11, 2021
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1. PURPOSE

- 1.1. Federal regulations require that the IRB establish procedures for concurrent monitoring of research activities involving human subjects. Periodic review of research activities may be necessary to determine whether the research should be continued, modified, or terminated.
- 1.2. IRB approval for the conduct of a study may be withdrawn if the risks to the subjects are determined to be unreasonably high (e.g., there is evidence that more than an expected number of adverse events have occurred, or the investigator is not conducting the research investigation in compliance with the approved protocol or institutional guidelines). Such findings may result in more frequent review of the study to determine if approval should be withdrawn or enrollment stopped until corrective measures can be instituted or the study terminated. Methods of monitoring ongoing research include, but are not limited to, the following activities:
 - Review of verification of protocol procedures;
 - Review of reports of complaints or concerns from participants;
 - Review of reports of unanticipated problems or adverse events;
 - Review of requested revisions to a protocol;
 - Review of reports of noncompliance;
 - Review of significant new findings;

2. POLICY and PROCEDURE

2.1. Site Visits and Verification

The IRB has the authority to observe, or have a third party observe, the informed consent process of research it has approved, and/or verify that the study is being conducted as required by the IRB approved protocol, within federal regulations, and institutional policies and procedures.

2.2. Review of Unanticipated Problems and Serious Adverse Events

Safety to the research participants is of great importance. The investigator must promptly report unanticipated problems involving serious risk or harm to the subjects and/or adverse events to the IRB.

2.3. Review of Requests for Amendments

Changes in the approved research, during the period for which approval has already been granted, may not be initiated without prior IRB review and approval, or a determination of exemption, except when necessary to eliminate an apparent immediate risk to the human subjects.

2.4. Review of Significant New Findings

During the course of a study, the IRB may review various sources of information, such as current literature, adverse event reports, or other sources to ascertain the status of a

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study and assess whether the risk/benefit ratio is still appropriate to the subject population, given the context of the research. The IRB will also determine if new information needs to be conveyed to the subjects.

2.5. Review of Complaints or Concerns

It is the responsibility of the IRB staff and IRB members to act on information or reports of complaints or concerns received from sources indicating that a study being conducted may not be in accordance with the approved protocol and/or institutional policies and procedures.

2.6. Review of Reports of Noncompliance

All reports of noncompliance must be reviewed by the IRB Chair/Designee and Research Integrity Office to determine whether a formal investigation needs to occur. If a formal investigation occurs, the results of the investigation will be reported to IRB, the IO, as well as any appropriate University official(s), if required. Reports of noncompliance may be a result of a review of complaints or concerns received and may be reported by any individual such as IRB members, investigators, subjects, personnel, anonymous sources, etc.

3. SCOPE

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

4. RESPONSIBILITY

The IRB staff, IRB Chair, and Research Integrity Director are responsible for ensuring that the review processes for conducting ongoing reviews of the research are conducted as appropriate.

References:

45 CFR 46 Regulations

UC Berkeley Policies and Procedures