

University of California, San Diego
Human Research Protections Program
Institutional Review Board
Standard Operating Policies and Procedures

Section 1.3
Review and Updating of SOPPs

Policy

The Standard Operating Policy and Procedures (SOPPs) of the Institutional Review Boards must remain current and in compliance with all applicable regulations. To remain current, the SOPPs are reviewed and periodically updated. The review process will update these policies and procedures to comply with the most recent federal, state, University of California, and UCSD regulations. This review will be documented. Notifications of changes and an updated SOPP will be made available to members of the IRBs, HRPP staff, as appropriate, and posted on the HRPP website at <https://irb.ucsd.edu>.

Procedures

1. Steering Committee
 - a) Review the SOPPs as needed, as determined by an IRB Chair, members of the Steering Committee, the IRB Director, an IRB Associate Director, and/or a majority of the IRB members.
 - b) Document the review and updating of SOPP(s) by including a revision date on the SOPP and a synopsis of revisions made to the SOPP on the HRPP website.
2. IRB Chairs and IRB Director
 - a) Review and approve each SOPP. Approval of an SOPP is documented by either signature, electronic signature, or e-mail from each IRB Chair and IRB Director specifically noting the SOPP(s) that has/have been approved or by using the following procedures:
 1. The IRB Chairs and IRB Director as well as the other members of the Steering Committee are provided with a revised/new SOPP for review and approval.
 2. The Committee has 14 days for review and to request any revisions.
 3. If no request(s) for revision(s) is/are provided within 14 days after the revised/new SOPP has been provided to the Steering Committee, the SOPP is approved.
 4. If request(s) for revision is/are provided, the SOPP will be revised, and the revised SOPP will be provided to the IRB Chairs and IRB Director.
 5. If no request(s) for revision(s) is/are provided within 7 days after the revised SOPP has been provided to the IRB Chairs and IRB Director, the SOPP is approved.

6. If any request(s) for revision(s) is/are provided during the 7 day period, the SOPP will reviewed at the next Steering Committee meeting.
7. At any time during the review of a revised/new SOPP, any Steering Committee member may request that the revised SOPP be reviewed at the next Steering Committee meeting.

An SOPP becomes effective once approval has been obtained, and the SOPP has been posted on the HRPP website.

3. IRB Members
 - a) Review and discuss changes made in SOPPs.
4. IRB Director
 - a) Retain file copies of current and archive copies of previous SOPPs.
 - b) Inform IRB members of changes made to SOPPs.
5. HRPP Web Editor
 - a) Create readable/downloadable versions of SOPPs for access by IRB Chairs, IRB members, HRPP staff as well as the research community at large.
 - b) Update the HRPP website to post the revised SOPP and a synopsis of the revision(s) made to each SOPP.

Applicable Regulations

[21 CFR 56.108\(a\)](#)

[21 CFR 56.115 \(6\)](#)

[45 CFR 46.103 \(b\) \(4\)](#)

[45 CFR 46.108 \(a\)](#)

[45 CFR 46.115 \(6\)](#)