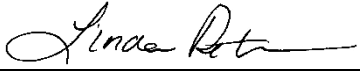



Standard Operating Procedures		
SOP #106.1 Revision 1	TITLE: Standard Operating Procedure Preparation, Issuance and Management	Effective Date: 3/1/2019
Approved By: OIRB Director	Signature 	Date 3/1/2019
Approved By: IRB Chair	Signature 	Date 3/1/2019

PURPOSE

To describe the policies and procedures for developing, reviewing, revising, and distributing standard operating procedures (SOPs) for the Institutional Review Board (IRB).

REVISIONS FROM PREVIOUS VERSION

Administrative corrections including parties involved in the process and dating

POLICY

The University of New Mexico (UNM) Office of the IRB (OIRB) maintains SOPs to ensure effective functioning of the UNM IRB. The OIRB documents when procedures are initiated, revised, and disseminated to staff, IRB members, principal investigators, and researchers as well as the procedures for staff training regarding SOPs and maintenance of training records.

RESPONSIBILITIES

Execution of SOP: OIRB Director, OIRB Staff, IRB, Principal Investigator (PI)/Researchers.

PROCEDURE

Writing Standard Operating Procedures

The OIRB Director, with advice from OIRB staff, IRB Chair, Vice Chair, IRB members and/or researchers determines when a new SOP needs to be established. Designated OIRB staff are responsible for writing SOPs. Any OIRB staff member may draft an SOP based on their expertise. All SOPs are in compliance with federal, state, and institutional regulations.

1. OIRB staff consult with the IRB Chairs and/or IRB members on IRB related issues in developing the SOPs.
2. As appropriate, the OIRB staff distribute copies of newly drafted SOPs to designated IRB Chairs, IRB members, and/or OIRB staff members for review.
3. If the SOP involves coordination with another University administrative office, the OIRB Director, or OIRB staff cooperate with the administrative unit to coordinate procedures.
4. The most recent revision date listed on an SOP indicates the version that is currently in effect. These dates are also available on the OIRB website.
5. Each SOP contains a revision number, which indicates how many times since its origination OIRB staff have revised an SOP.
6. Approved SOPs will be signed by the OIRB Director and the IRB Chair.

Dissemination of Standard Operating Procedures

1. The OIRB Director monitors the SOPs and disseminates new SOPs to all OIRB staff members and to the IRB members if the SOP involves their activities.
2. OIRB Staff sign the SOP Training Log after their review of new SOPs.
3. The OIRB maintains the most recent versions of all approved SOPs on the OIRB website. OIRB staff provide information on the availability of the SOPs through a variety of educational initiatives.
4. Researchers are responsible for reviewing and complying with ethical codes, IRB guidance documents, OIRB/IRB SOPs relevant to them, to professional practice, and to other applicable regulatory requirements.
5. The OIRB Director or designee informs institutional officials of all new and revised SOPs when appropriate.

Revisions to Standard Operating Procedures

1. The OIRB Director, with advice from OIRB staff, IRB Chair, Vice Chair, and/or IRB members, determines when to revise an existing SOP. The OIRB may make minor administrative corrections without revising an SOP (e.g. typographical or grammatical error). Any OIRB staff member may draft revisions to an SOP based on their expertise. All SOP revisions are in compliance with federal, state, and institutional regulations.
2. In revising SOPs, OIRB staff will follow the same procedures for *Writing Standard Operating Procedures*.
3. OIRB staff places an updated copy of a revised SOP in the OIRB database, the SOP binder, and posts the updated SOP to the OIRB website. OIRB staff and/or IRB members will be advised of the revisions and sign the SOP Training Log.
4. The OIRB Director informs OIRB staff members of all changes in the SOPs that are relevant to their job functions via individual meetings, presentations at staff meetings and if applicable through published announcements.
5. OIRB staff informs IRB members of all changes in SOPs that are relevant to their responsibilities and provides this information via email, presentations and/or the OIRB website.
6. If an SOP impacts researchers, OIRB staff provides this information to them through the OIRB website and disseminates changes through a variety of educational initiatives (e.g. list serve announcements, newsletters, presentations).

Temporary Addendums for Transitional Periods or Emergency Situations

1. The OIRB Director or designee has the authority to implement temporary contingency procedures that may veer from designated SOPs in emergency situations or during transitional periods.
2. The OIRB Director or designee will document temporary contingency procedures and the period in which they are in affect via an SOP addendum to the applicable SOP. The addendum will be signed and dated by the OIRB Director.

Review of Standard Operating Procedures

1. The OIRB Director or designee conducts an annual review, or according to workload or need, of the continuing suitability of the SOPs.
2. OIRB staff may review SOPs at any time for accuracy/applicability. The IRB/OIRB staff obtain information necessary to update procedures through monitoring of sources including, but not limited to, AAHRPP standards, the U.S. Food & Drug Administration website, Department of Health & Human Services, and the Office for Human Research Protections listserv.

3. If significant or applicable changes to procedures become necessary, OIRB staff will follow Revisions to Standard Operating Procedures.

Suspension or Deletion of a SOP

1. Upon consulting with IRB Chairs, the OIRB Director has authority to suspend or delete a SOP in such circumstances as major policy deliberation, changes in institutional administration, or reorganization of departments, offices or divisions with which the OIRB and IRB have coordination relationships or joint procedures.
2. When an SOP is suspended or becomes obsolete, the OIRB Director deletes the SOP, informs appropriate staff and/or IRB members, and ensures that OIRB staff remove the SOP from the OIRB website, SOP binder, and database and archive it, as appropriate.

Record Keeping

1. OIRB staff maintains copies of all current SOPs in both hard copy and electronic files. The designated OIRB staff person archives copies of all previous editions of the SOPs in the SOP binder.
2. OIRB staff files the SOPs in the SOP binder, and places the electronic files into the SOP folder in the OIRB system. The OIRB maintains copies of all original and subsequent revisions of all SOPs indefinitely.
3. Current SOPs are available on the OIRB website.