### Standard Operating Procedures

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<tr>
<th>SOP #106.0 Revision 0</th>
<th>TITLE: Standard Operating Procedure Preparation, Issuance and Management</th>
<th>Effective Date: 6/1/2015</th>
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<tr>
<td>Approved By:</td>
<td>Signature</td>
<td>Date</td>
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<tr>
<td>OIRB Director</td>
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<td>6/2/15</td>
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<td>Approved By:</td>
<td>Signature</td>
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<td>IRB Chair</td>
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**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**
None

**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, Principal Investigator (PI)/Study Personnel, Associate Vice President for Research Compliance.

**PROCEDURE**
*Writing Standard Operating Procedures*

The OIRB Director, with advice from OIRB staff, IRB Chairs, Vice Chairs, 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 his/her 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 involved in drafting the SOP and route the SOP to the appropriate individual representing that office for approval and signature.

4. The OIRB staff ensure that each SOP designates the date on which it originally became effective as well as the most recent revision date, which serves as the currently effective date for the SOP. The most recent revision date indicates that this version is currently in effect.

5. Each SOP contains a revision number, which indicates how many times since its origination OIRB staff have revised an SOP. These dates are also available on the OIRB website.

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. The OIRB Director also circulating a SOP Tracking Form to applicable OIRB staff for their signature to document circulation and 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, and 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 Chairs, Vice Chairs, 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 his/her 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.

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, 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 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.