

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures			
SOP #1-5 Revision #8	TITLE: Generation, Use, and Revision of Standard Operating Procedures		Page 1 of 5
Approved By: ORI Director	Signature	Date	Date First Effective: 06-19-05
Approved By: Nonmedical IRB Chair	Signature	Date	
Approved By: Medical IRB Chair	Signature	Date	Revision Date:10/22/10

OBJECTIVE

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

GENERAL DESCRIPTION

The University of Kentucky (UK) IRB and the ORI maintain standard operating procedures to ensure effective functioning of the UK human research protection program. The ORI documents when procedures are initiated, revised, and disseminated to staff, IRB members, investigators, and study personnel as well as the procedures for staff training regarding SOPs and maintenance of training records.

RESPONSIBILITY

Execution of SOP: ORI Director, ORI Staff, ORI Quality Improvement Program (QIP) Coordinator, Research Education Specialist (RES), Principal Investigator (PI)/Study Personnel, Vice President for Research (VPR).

PROCEDURES

Procedure for Writing Standard Operating Procedures

1. The ORI Director, with advice from ORI staff, IRB Chairs, Vice Chairs, IRB members and/or investigators determines when a new SOP needs to be established. Designated ORI staff are responsible for writing SOPs.

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #1-5 Revision #8	TITLE: Generation, Use, and Revision of Standard Operating Procedures (SOPs)	Page 2 of 5

2. Any ORI staff member may draft an SOP based on his/her specialization. All SOPs are in compliance with federal, state, and institutional regulations.
3. ORI staff consult with the IRB Chairs and/or IRB members on IRB related issues in developing the SOPs.
4. As appropriate, the ORI staff distribute copies of newly drafted SOPs to designated IRB Chairs, IRB members, and/or ORI staff members for review.
5. If the SOP involves coordination with another University administrative office, the ORI Director, or ORI 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.
6. The ORI 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.
7. Each SOP contains a revision number, which indicates how many times since its origination ORI staff have revised an SOP. These dates are also available on the ORI website.
8. The ORI Director, IRB Chairs, and any appropriate coordinating officials sign and date each SOP.

Dissemination of Standard Operating Procedures

1. The RES or designee monitors the SOPs and disseminates new SOPs to all ORI staff members and to the IRB Chairs, Vice Chairs, or members if the SOP involves their activities.
2. The RES also circulates a SOP Tracking Form to applicable ORI staff for their signature to document circulation and review of new SOPs.
3. ORI staff and/or IRB Chairs or designees are responsible for reviewing the new SOP, signing the attached SOP Tracking Form, and returning it to the RES within a reasonable amount of time.
4. The ORI maintains the most recent versions of all approved SOPs on the ORI website. ORI staff provide information on the availability of the SOPs through a variety of educational initiatives [e.g., *the Institutional Review Board (IRB) Survival Handbook*].

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #1-5 Revision #8	TITLE: Generation, Use, and Revision of Standard Operating Procedures (SOPs)	Page 3 of 5

5. According to the ORI guidance document, “A Principal Investigator’s Guide to Responsibilities, Qualifications, Records, and Documentation of Human Subjects Research”, PIs are responsible for reviewing and complying with ethical codes, IRB guidance documents, and ORI/IRB SOPs relevant to them, to professional practice, and to other applicable regulatory requirements.

Revisions to Standard Operating Procedures

1. The ORI Director, with advice from ORI staff, IRB Chairs, Vice Chairs, and/or IRB members, determines when to revise an existing SOP. In most cases, the RES revises the SOP. The RES may make minor administrative corrections without revising an SOP (e.g. typographical or grammatical error). Any ORI staff member may draft revisions to an SOP based on his/her specialization. All SOP revisions are in compliance with federal, state, and institutional regulations.
2. In revising SOPs, ORI staff may consult with IRB Chairs and/or IRB members on IRB related issues.
3. As appropriate, the RES circulates copies of newly revised SOPs to IRB Chairs, IRB members, and/or ORI staff for review.
4. If the revised SOP involves coordination with another University administrative office, the RES routes the SOP to the appropriate individual representing that office for review, approval, and signature.
5. The revised SOP becomes effective when signed by the ORI Director or designee, IRB Chairs, and coordinating official(s) on the date indicated.
6. The RES places an updated copy of a revised SOP in the ORI database and the SOP binder he/she maintains. The designated ORI staff person also posts the updated SOP to the ORI website and advises ORI staff and/or IRB members of the revisions.
7. The RES informs ORI 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.
8. The RES informs IRB members of all changes in SOPs that are relevant to their responsibilities and provides this information via direct mailings, presentations and/or the

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #1-5 Revision #8	TITLE: Generation, Use, and Revision of Standard Operating Procedures (SOPs)	Page 4 of 5

ORI website.

9. If an SOP impacts investigators/study personnel, the RES or designee provides this information to them through the ORI website and disseminates changes through a variety of educational initiatives (e.g., list serve announcements, newsletters, presentations).
10. The ORI Director or designee informs institutional officials of all changes in the SOPs when appropriate.

Temporary Addendums for Transitional Periods or Emergency Situations

1. The ORI 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 ORI 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 ORI director.

Review of Standard Operating Procedures

1. The RES, QIP Coordinator, or designee conducts a periodic review, once a year, or according to workload or need, of the continuing suitability of the SOPs.
2. ORI staff may review SOPs at any time for accuracy/applicability. The IRB/ORI 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, the ORI Director, or RES revise the SOP in question as soon as possible, and the RES distributes the revisions to the IRB, ORI staff, and appropriate individuals representing coordinating administrative offices in a timely manner following the procedures outlined above. (See the section on *Revisions to Standard Operating Procedure.*)

Suspension or Deletion of a SOP

1. Upon consulting with IRB Chairs, the ORI Director has authority to suspend or delete a SOP in such circumstances as major policy deliberation, changes in institutional administration, or

University of Kentucky Office of Research Integrity and Institutional Review Board Standard Operating Procedures		
SOP #1-5 Revision #8	TITLE: Generation, Use, and Revision of Standard Operating Procedures (SOPs)	Page 5 of 5

reorganization of departments, offices or divisions with which the ORI and IRB have coordination relationships or joint procedures.

2. When an SOP is suspended or becomes obsolete, the RES deletes the SOP, informs appropriate staff and/or IRB members, and ensures that ORI staff remove the SOP from the ORI website and database and archive it, as appropriate.

Record Keeping

1. The RES maintains copies of all current SOPs in both hard copy and electronic files. The designated ORI staff person archives copies of all previous editions of the SOPs in the SOP binder.
2. The RES files the SOPs in the SOP binder, and places the electronic files into the SOP folder in the ORI system. The RES or designee maintains copies of all original and subsequent revisions of all SOPs indefinitely.

REFERENCES

Not applicable