GENERATION, USE, AND REVISION OF STANDARD OPERATING PROCEDURES

The Franklin University IRB maintains standard operating procedures to ensure effective functioning of the University's human research protection program. The IRB Office documents when procedures are initiated and revised.

PROCEDURES

Procedure for Writing Standard Operating Procedures (SOPs)

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

2. All SOPs are in compliance with federal, state, and institutional regulations.

3. As needed, IRB staff consult with the Institutional Official, IRB Chair and/or IRB members on IRB related issues in developing the SOPs.

4. As appropriate, IRB staff distribute copies of newly drafted SOPs to the IRB Chair and IRB members for review.

5. If the SOP involves coordination with another University administrative office, the IRB Manager cooperates with the administrative unit involved in drafting the SOP and routes the SOP to the appropriate individual representing that office for approval.

6. IRB 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.

Dissemination of Standard Operating Procedures

1. The IRB Manager disseminates new SOPs to all IRB members.

2. The IRB Office maintains the most recent versions of all approved SOPs on the Franklin University IRB website. IRB staff provide information on updates and the availability of the SOPs through a variety of educational initiatives [e.g., faculty emails, various University meetings].

Revisions to Standard Operating Procedures

1. The IRB Manager, with advice from IRB staff, the IRB Chair, and/or IRB members, determines when to revise an existing SOP.

2. In revising SOPs, IRB staff may consult with the IRB Chair and/or IRB members on IRB related issues.

3. As appropriate, the IRB Manager circulates copies of newly revised SOPs to the IRB Chair, IRB members, and/or IRB staff for review.

4. If the revised SOP involves coordination with another University administrative office, the IRB Manager routes the SOP to the appropriate individual representing that office for review and approval.

5. The IRB Manager posts the updated SOP to the IRB website.

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6. If an SOP impacts investigators/study personnel, the IRB Office provides this information to them through the IRB website and disseminates changes through a variety of educational initiatives (e.g., list serve announcements, presentations).

Temporary Addendums for Transitional Periods or Emergency Situations

1. The IRB Manager has the authority to implement temporary contingency procedures that may veer from designated SOPs in emergency situations or during transitional periods.

Review of Standard Operating Procedures

1. The IRB Manager conducts a periodic review, at least once a year, or according to workload or need, of the continuing suitability of the SOPs.

2. IRB staff may review SOPs at any time for accuracy/applicability. IRB staff obtain information necessary to update procedures through monitoring of sources including, but not limited to, the U.S. Department of Health & Human Services and the Office for Human Research Protections.

3. If significant or applicable changes to procedures become necessary, the IRB Manager will revise the SOP in question as soon as possible and distribute the revisions to the IRB and appropriate individuals representing coordinating administrative offices in a timely manner.

Suspension or Deletion of a SOP

1. Upon consulting with the IRB Chair, the IRB Manager has authority to suspend or delete an SOP in such circumstances as major policy deliberation, changes in institutional administration, or reorganization of departments, offices or divisions with which the IRB Office and IRB have coordination relationships or joint procedures.

2. When an SOP is suspended or becomes obsolete, the IRB Manager deletes the SOP, informs appropriate staff and/or IRB members, and ensures removal of the SOP from the IRB website.

Recordkeeping

1. The IRB Office maintains copies of all current SOPs in electronic files. The IRB Manager archives copies of all previous editions of the SOPs.

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