Policy Number: 102.1
Effective Date: 4/11/2022
SOP Owner: HRC

Standard Operating Procedure Preparation, Issuance, and Management

I. Purpose

To describe the process for developing, reviewing, revising, and distributing standard operating procedures (SOPs) for the human research protections program (HRPP).

II. Revisions from Previous Version

None.

III. Definitions

None.

IV. Policy

The Weill Cornell Medicine (WCM) Human Research Compliance (HRC) office maintains SOPs to ensure effective functioning of the WCM IRB and facilitates the HRPP. The HRC office documents when procedures are initiated, revised, and disseminated to IRB staff, IRB members, researchers, and other HRPP stakeholders as well as the procedures for staff training regarding SOPs and maintenance of training records.

V. Procedure

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

1. As appropriate, IRB staff consult with the IRB Chairs, Vice Chairs, and/or members on IRB related issues in developing the SOPs.
2. As appropriate, the IRB staff distribute copies of newly drafted SOPs to designated IRB Chairs, Vice Chairs, members, and/or IRB staff for review.
3. If the SOP involves coordination with another University administrative office, the HRC Executive Director, or IRB staff cooperate with the administrative unit to coordinate procedures.
4. The effective date listed on an SOP indicates the version that is currently in effect.
5. Each SOP contains a revision number, which indicates how many times since its origination IRB staff have revised an SOP.

Dissemination of SOPs

1. The HRC Executive Director or designee monitors the SOPs and disseminates new SOPs to all IRB staff members and to the IRB members if the SOP involves their activities.
2. IRB staff training on SOPs is documented, including training on revisions.
3. The current versions of all SOPs on the IRB website. IRB 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, IRB SOPs relevant to them, to professional practice, and to other applicable regulatory requirements.
5. The HRC Executive Director or designee informs institutional officials of all new and revised SOPs when appropriate.

Revisions to SOPs

1. The HRC Executive Director or designee, with advice from IRB staff, Chairs, Vice Chairs, and/or members, determines when to revise an existing SOP. The IRB may make minor administrative corrections without revising an SOP (e.g., typographical or grammatical error). Any IRB 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, IRB staff will follow the same procedures for *Writing Standard Operating Procedures.*
3. IRB staff post an updated copy of a revised SOP to the IRB website. IRB staff and/or IRB members will be advised of the revisions and training will be documented.
4. The HRC Executive Director or designee informs IRB 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 announcements.
5. IRB 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 IRB website.
6. If an SOP impacts researchers, IRB staff provides this information to them through the IRB website and disseminates changes through a variety of educational initiatives (e.g. list serve announcements, newsletters, presentations, etc.).

Temporary Addendums for Transitional Periods or Emergency Situations

1. The HRC Executive 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 HRC Executive 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.

Review of SOPs

1. The HRC Executive Director or designee conducts an annual review, 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. The IRB 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, the Office for Human Research Protections listserv, or other appropriate regulatory office.
3. If significant or applicable changes to procedures become necessary, IRB staff will follow Revisions to SOPs.

Suspension or Deletion of SOPs

1. The HRC Executive 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 IRB staff and IRB members have coordination relationships or joint procedures.
2. When an SOP is suspended or becomes obsolete, the HRC Executive Director deletes the SOP, informs appropriate staff and/or IRB members, and ensures that removal from the IRB website, and archive it, as appropriate.

Record Keeping

1. IRB staff maintain copies of all current SOPs as electronic files. Designated IRB staff archive copies of all previous editions of the SOPs in HRC electronic records.
2. The IRB maintains copies of all original and subsequent revisions of all SOPs indefinitely. Current SOPs are available on the IRB website.

VI. References

None.