

Generation, Use, and Revisions of SOPs			
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1 PURPOSE

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 Human Research Protections (OHRP) at West Virginia University (WVU).

2 OVERVIEW

This SOP applies to all policies and procedures reviewed by VPR (Institutional Official or IO), WVU OHRP Director, WVU OHRP Assistant Director (OAD), WVU OHRP Continuous Improvement Manager (CIM), WVU OHRP staff, and approved by WVU IRB Leadership, the Vice President for Research (VPR), and any WVU administrative offices to which the SOP applies.

3 PROCEDURES

Procedure for Writing New Standard Operating Procedures

- 3.1. The WVU OHRP Director, with advice from IO, OAD, CIM, WVU OHRP staff, IRB Chairs, IRB Vice Chairs, IRB members, and/or PIs (as applicable), determines when a new SOP needs to be established. Designated OHRP staff are responsible for writing SOPs.
- 3.2. Any OHRP Staff member may draft an SOP based on his or her specialization. All SOPs should comply with federal, state, and institutional regulations.
- 3.3. As appropriate, the WVU OHRP staff distribute copies of newly drafted SOPs to designated IRB Chairs, IRB Vice Chairs, IRB members, and/or OHRP staff members for review.
- 3.4. If the SOP involves coordination with another WVU administrative office, the WVU OHRP Director or WVU OHRP staff cooperate with the administrative unit involved in drafting the SOP and route the SOP to the appropriate individual representing that office for approval.
- 3.5. The WVU OHRP staff ensure each SOP designates the most recent revision date, which serves as the currently effective date for the SOP.
- 3.6. Each SOP contains a version number, which indicates how many times since its origination, WVU OHRP staff have revised an SOP.
- 3.7. The IRB Chair(s), WVU's VPR, and any appropriate coordinating officials (when necessary) review the new or revised SOP. The SOP approval documentation is used to track new and revised SOP approvals. The SOP approval documentation will denote which SOP(s) were reviewed and approved, along with the original version number. The date that the VPR (IO) reviews and approves the SOP(s) should match the currently effective date of an SOP.

Dissemination of Standard Operating Procedures

- 3.8. The OAD or designee monitors the SOPs and disseminates new SOPs to all WVU OHRP staff members and to the IRB Chairs, Vice Chairs, or members if the SOP involves their activities.
- 3.9. WVU OHRP staff and/or IRB Chairs or designees are responsible for reviewing the new SOP, documenting their review, and returning it to the OAD within a reasonable amount of time.

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- 3.10. The WVU OHRP maintains the most recent versions of all approved SOPs on the WVU OHRP website.
- 3.11. According to SOP 003 (Investigator and Key Personnel Responsibilities, Qualifications, and Training), PIs are responsible for reviewing and complying with ethical codes, IRB guidance documents, and WVU OHRP/IRB SOPs relevant to them, to professional practice, and to other applicable regulatory requirements (e.g., 45 CFR 46.114 – Cooperative Research Provision).

Revisions to Standard Operating Procedures

- 3.12. The WVU OHRP Director, with advice from VPR (IO), OAD, CIM, WVU OHRP staff, IRB Chairs, Vice Chairs, and/or IRB members, determines when to revise an existing SOP. In most cases, the OAD revises the SOP. The OAD may make minor administrative corrections without revising an SOP (e.g., typographical, formatting, or grammatical error). Any WVU OHRP staff member may draft revisions to an SOP based on his or her specialization. All SOP revisions should comply with federal, state, and institutional regulations.
- 3.13. In revising SOPs, WVU OHRP staff may consult with IRB Chairs and/or IRB members on IRB-related issues.
- 3.14. As appropriate, the OAD or designee circulates copies of newly revised SOPs to IRB Chairs, IRB members, and/or WVU OHRP staff for review.
- 3.15. If the revised SOP involves coordination with another WVU administrative office, the OAD or designee routes the SOP to the appropriate individual representing that office for review and approval.
- 3.16. The revised SOP is effective when the SOP documentation is approved by the WVU VPR (in coordination with IRB Chairs and any other coordinating officials [as necessary] on the date indicated).
- 3.17. The CIM or designee places an updated copy of a revised SOP in the WVU OHRP Sharepoint secured site where effective SOPs and SOP approval documentation are stored.
- 3.18. The CIM or designee informs WVU OHRP staff members of all changes in the SOPs relevant to their jobs.
- 3.19. The CIM or designee informs IRB members of all changes in SOPs relevant to their responsibilities and provides this information via virtual or in-person meetings, email, communication, presentations, and/or the OHRP website.
- 3.20. If an SOP impacts PIs or study personnel, the CIM or designee provides this information to them through the WVU OHRP website and may disseminate changes through various educational initiatives (e.g., emails, listserv announcements, newsletters, presentations, etc.).

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Temporary Addendums for Transitional Periods or Emergency Situations

- 3.21. The WVU OHRP Director or designee has the authority to implement temporary contingency procedures that may veer from designated SOPs in emergency situations or during transitional periods.
- 3.22. The WVU OHRP Director or designee will document temporary contingency procedures and the period in which they are in effect via an SOP addendum to the applicable SOP. The addendum will be confirmed in writing (electronic or paper) by the WVU OHRP Director or designee.

Review of Standard Operating Procedures

- 3.23. The OAD or designee conducts a periodic review (once every three years or according to workload/need) of the continuing suitability of the SOPs.
- 3.24. WVU OHRP staff may review SOPs at any time for accuracy/applicability. The WVU IRB/OHRP staff obtain information necessary to update procedures through monitoring of sources including, but not limited to, the US Food and Drug Administration website and the Department of Health and Human Services.
- 3.25. If significant or applicable changes to procedures become necessary, the WVU OHRP Director, OAD, or designee revises the SOP in question as soon as possible, and the OAD or designee distributes the revisions to the IRB, WVU OHRP 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 Procedures*.)

Suspension or Deletion of an SOP

- 3.26. Upon consulting with IRB Chairs, the WVU OHRP Director or designee has the 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 WVU OHRP and IRB have coordinated relationships or joint procedures.
- 3.27. When an SOP is suspended or becomes obsolete, the CIM or designee deletes the SOP, informs appropriate staff and/or IRB members, and ensures that WVU OHRP staff remove the SOP from the WVU OHRP website and database, and archive or delete it, as appropriate, and within WVU's institutional data destruction policies.

Record Keeping

- 3.28. The CIM or designee maintains copies of all current SOPs on the WVU OHRP Website and OHRP Sharepoint secured site. (See SOP 039: IRB Records and Data Information Management.)

4 REFERENCES

Not applicable