



SOP: Standard Operating Procedures

1 PURPOSE

- 1.1 This procedure establishes the process to create and update standard operating procedures and associated checklists and worksheets.
- 1.2 The process begins when the IRB manager or Institutional Official/ Organizational Official (IO/OO) or designee determines that a standard operating procedure needs to be created or modified.
- 1.3 The process ends when the new or revised standard operating procedure has been approved and filed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 None

4 RESPONSIBILITIES

- 4.1 The IRB director carries out these procedures.

5 PROCEDURE

- 5.1 For a new standard operating procedure, assign a number.
- 5.2 Assign an author and approver.
- 5.3 Have the author create or update the standard operating procedure following HRP-505 - TEMPLATE SOP or update the associated checklist or worksheet.
- 5.4 Have the approver review and approve the document.
- 5.5 Once approved by the approver:
 - 5.5.1 Update the approval/effective date.
 - 5.5.2 File and maintain the approved new or revised document in the standard operating procedure files.
 - 5.5.3 Post the approved procedure on the Human Research Protection Program Web site.
 - 5.5.4 File and retain the previous version in the standard operating procedure files.
 - 5.5.5 Send an email to affected individuals informing them of the change.

6 MATERIALS

- 6.1 HRP-505 - TEMPLATE SOP

7 REFERENCES

- 7.1 AAHRPP elements I-9, II.5.A