

SOP: Toolkit Management

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 For all new or revised standard operating procedures, review is conducted of all associated Toolkit documents and if additional changes are warranted, each document is updated per the procedures below.

4 RESPONSIBILITIES

- 4.1 The IRB manager carries out these procedures.

5 PROCEDURE

- 5.1 For a new Toolkit document:
 - 5.1.1 Assign a number.
 - 5.1.2 Assign an author and approver.
 - 5.1.3 Have the author create the standard operating procedure following HRP-505 - TEMPLATE SOP.
 - 5.1.4 Have the approver review and approve the document.
- 5.2 For a revision to a previously approved Toolkit documents:
 - 5.2.1 Edit the current document using the tracked changes feature in MS Word.
 - 5.2.2 Update Section 2 (Revisions from Previous Version) and include:
 - 5.2.2.1 A short summary of changes,
 - 5.2.2.2 The date of the most recent previous approval.
 - 5.2.3 Have the approver review and approve the document.
- 5.3 Once approved by the approver:
 - 5.3.1 Update the approval/effective date.
 - 5.3.2 File and maintain the approved revised document in the standard operating procedure files.
 - 5.3.3 When necessary, update HRP-100 - HRPP Toolkit Table of Contents, HRP-105 - OHRP FDA Written Procedure Crosswalk, and all other applicable Toolkit documents to reflect the new/revised document.
 - 5.3.4 Post the approved procedure on the Human Research Protection Program Web site.
 - 5.3.5 File and retain the previous version in the standard operating procedure files.
 - 5.3.6 Send an email to affected individuals informing them of the change.

6 MATERIALS

- 6.1 HRP-100 - HRPP Toolkit Table of Contents
- 6.2 HRP-105 - OHRP FDA Written Procedure Crosswalk
- 6.3 HRP-505 - TEMPLATE SOP

7 REFERENCES

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