



SOP: Standard Operating Procedures				
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**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 Executive Director of the HSRO, the 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 Revision to the title of individual who determines when a standard operating procedure is needed or requires modification.
- 2.2 Revision to add requirement for SOP review and log to document review.
- 2.3 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

**3 GUIDING PRINCIPLES**

- 3.1 Written operating procedures compliant with federal regulations and guidance, and HSRO SOPs must be in place to ensure the highest quality and integrity of the review and oversight of research involving human subjects and for the adequate documentation of such oversight.
- 3.2 Each approved SOP will be reviewed no less than three years from the date of approval as described in this policy. The review date is determined as three years from the last date of approval.
- 3.3 SOPs will be updated, as applicable, when new or revised regulations are promulgated and when new regulatory guidance becomes available

**4 RESPONSIBILITIES**

- 4.1 The Executive Director of the HSRO or designee 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 the HRP-505 - TEMPLATE 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 date.
  - 5.5.2 File 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 the old document, if any, in the standard operating procedure files.
  - 5.5.5 Send an email to affected individuals informing them of the change.
  - 5.5.6 Schedule training, as applicable, for affected individuals.
  - 5.5.7 Record the above actions on the HSRO SOP Log.
- 5.6 Access the HSRO SOP Log on a regular basis to determine SOPs that require reviewed
  - 5.6.1 Review SOPs that are expiring.
  - 5.6.2 If no revision are required, document the results of the review in the HSRO SOP Log.

**6 MATERIALS**

- 6.1 HRP-505 - TEMPLATE SOP
- 6.2 HSRO SOP Log



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**7 REFERENCES**

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