

SOP: Standard Operating Procedures

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| 1.010 (HRP-071) | 7/17/24 | 1 of 1 |

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 Institutional Official, Assistant Vice President of Research Regulatory Affairs, HRPP Director, QA&E Director or designee determines that a standard operating procedure or related document needs to be created or modified.
- 1.3 The process ends when the new or revised standard operating procedure or related document has been approved and filed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 4/17/24.

3 POLICY

- 3.1 None.

4 RESPONSIBILITIES

- 4.1 The HRPP Director, QA&E Director, or designee carries out these procedures.

5 PROCEDURE

- 5.1 For a new standard operating procedure, assign a Toolkit number.
- 5.2 Assign an author and approver.
- 5.3 Have the author create or update the standard operating procedure following **1.301 (HRP-505) – Generic Template for Any 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 Notify affected individuals of the Toolkit change(s).

6 MATERIALS

- 6.1 1.301 (HRP-505) – TEMPLATE - Generic Template of Any SOP.

7 REFERENCES

- 7.1 None.