



## SOP: Standard Operating Procedures

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-071	Executive Director, IRB Office Northwestern University	01/21/2019	Page 1 of 1

### 1 PURPOSE

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

### 2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 11/22/2018.

### 3 POLICY

- 3.1 Each approved standard operating procedure will be reviewed no less than three years from the effective date.

### 4 RESPONSIBILITIES

- 4.1 The IRB Office Executive Director, IRB Manager, or designee carries out these procedures.

### 5 PROCEDURE

- 5.1 For a new standard operating procedure, assign a HRP number, if applicable.
- 5.2 Create or update the standard operating procedure following the "TEMPLATE SOP (HRP-505)" or update the associated checklist or worksheet.
- 5.3 Approved standard operating procedures will be reviewed no less than three years from the effective date to ensure alignment with current IRB Office procedures, and compliance with federal and state regulations, and Northwestern University policies.
- 5.4 Revisions to the content of existing standard operating procedures will be made, only if changes are needed. If there are no changes needed at the time of the three year review, at a minimum the effective date will be updated to reflect the current approval date.
- 5.5 The Executive Director, IRB Office is responsible for the final review and approval of the document.
- 5.6 Once approved by the IRB Executive Director, the designated IRB Office staff will:
  - 5.6.1 Update the approval/effective date.
  - 5.6.2 File and maintain the approved new or revised document in the standard operating procedure files.
  - 5.6.3 Post the approved procedure on the IRB Office web site, if applicable.
  - 5.6.4 File and retain the previous version, if any, in the standard operating procedure files.
  - 5.6.5 Send an email to affected individuals informing them of the change.

### 6 MATERIALS

- 6.1 TEMPLATE SOP (HRP-505)

### 7 REFERENCES

- 7.1 None.