



## SOP: Toolkit Management

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-071	Executive Director, IRB Office Northwestern University	01/31/2025	Page 1 of 2

### 1 PURPOSE

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

### 2 PREVIOUS VERSION

- 2.1 Revised from the previous version dated 11/01/2024.

### 3 POLICY

- 3.1 Each tool or resource requiring periodic review will be reviewed no less than four years from the effective date.

### 4 RESPONSIBILITIES

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

### 5 PROCEDURE

- 5.1 For a new tool or resource, assign an HRP number, if applicable.
- 5.2 Create or update the standard operating procedure following the TEMPLATE: Template SOP (HRP-505). Create or update the associated material (checklist, worksheet, form, guidance, etc.) following the relevant templates.
- 5.3 The IRB Office Executive Director or designee will determine whether a tool or resource requires periodic review.
- 5.4 Approved tools and resources requiring periodic review will be reviewed no less than four years from the effective date to ensure alignment with current IRB Office procedures and compliance with federal and state regulations, and Northwestern University policies.
- 5.5 Revisions to the content of existing tools and resources will be made only if changes are needed. If there are no changes needed at the time of the four-year review, at a minimum, the effective date will be updated to reflect the current approval date.
- 5.6 The IRB Office Executive Director or designee is responsible for the final review and approval of tools and resources.
- 5.7 Once approved by the IRB Executive Director or designee, the designated IRB Office staff will:
  - 5.7.1 Update the approval/effective date.
  - 5.7.2 File and maintain the approved new or revised document in the current IRB Office electronic document management system.
  - 5.7.3 Post the approved procedure on the IRB Office website, if applicable.
  - 5.7.4 File and retain the previous version, if any, in the current IRB Office electronic document management system.
  - 5.7.5 Send an email to affected individuals informing them of the change, if applicable.

### 6 MATERIALS

- 6.1 TEMPLATE: Template SOP (HRP-505)



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NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
HRP-071	Executive Director, IRB Office Northwestern University	01/31/2025	Page 2 of 2

### 7 REFERENCES

7.1 None.