



## SOP: Establishing Authorization Agreements

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### 1 PURPOSE

- 1.1 This procedure establishes the process to execute an Authorization Agreement with an external institution/organization.
- 1.2 The process begins when an external IRB from another institution/organization has been identified by the Northwestern University IRB Office staff or Northwestern University research team, for a potential Authorization Agreement.
- 1.3 The process ends when the Authorization Agreement is fully executed.

### 2 PREVIOUS VERSION

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

### 3 POLICY

- 3.1 In accordance with Human Research Protection Program Plan (HRP-101), the Northwestern University IRB Office reviews and determines if it is appropriate to execute an Authorization Agreement for either:
  - 3.1.1 The Northwestern University IRB to serve as the Single IRB or IRB of Record for a Multi-Site Study or Collaborative Study, in alignment with the requirements outlined in “SOP: Northwestern University serving as IRB of Record (HRP-093)”, or
  - 3.1.2 The Northwestern University IRB to cede IRB review to (i.e. rely on) an External IRB from another institution/organization, in alignment with the requirements outlined in “SOP: External IRBs (HRP-092)”.
- 3.2 The Northwestern University IRB Office may leverage the SMART IRB agreement, utilize the other institution/organizations local Authorization Agreement, or utilize a Northwestern University standard Authorization Agreement template.

### 4 RESPONSIBILITIES

- 4.1 An IRB Office staff member of the Reliance Team carries out these procedures.

### 5 PROCEDURE

- 5.1 Upon receiving a request to execute an Authorization Agreement with an external institution/organization, the IRB Office staff member will review the request to determine if it is appropriate.
  - 5.1.1 If a valid Authorization Agreement is already in place, this process is complete.
  - 5.1.2 If no Authorization Agreement is in place, and one is required, proceed with step 5.2 below.
- 5.2 Use “WORKSHEET: Authorization Agreement Review (HRP-1801)” to verify all relevant criteria have been met.
- 5.3 Upon determining that the request for an Authorization Agreement is appropriate, complete the following:
  - 5.3.1 Document in the agreement the terms and conditions under which:
    - 5.3.1.1 Northwestern University’s IRB will serve as the IRB of Record for that institution/organization, using the standard Authorization Agreement “TEMPLATE: Northwestern University IRB\_IRB of Record”, or
    - 5.3.1.2 The External IRB will serve as the IRB of record for Northwestern University using the standard Authorization Agreement “TEMPLATE: Northwestern University IRB\_NOT IRB of record”
  - 5.3.2 Negotiate the terms of the agreement, if different from the standard template. Any non-standard language may require additional review and approval by:
    - 5.3.2.1 Executive Director, IRB Office



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- 5.3.2.2 Associate Vice President, Research
- 5.3.2.3 Office of General Counsel
- 5.3.2.4 Office for Sponsored Research
- 5.3.3 If the external institution/organization participates in SMART IRB and requests the use of the SMART IRB documentation, then determine if the SMART IRB agreement may be utilized in lieu of the Northwestern University standard Authorization Agreement template.
- 5.3.4 Forward the agreement to Northwestern University's Institutional Official or designated Signatory. Complete the execution of the agreement by ensuring all parties have signed the agreement and relevant parties have received the final executed copy.
- 5.4 If the criteria are not met, do not execute an Authorization Agreement. Communicate this to the external institution/organization and the Northwestern University research team, and work with all parties to resolve the issues, as appropriate.

## 6 MATERIALS

- 6.1 GENERAL DOCUMENT: Human Research Protection Program Plan (HRP-101)
- 6.2 GENERAL DOCUMENT: Investigator Manual (HRP-103)
- 6.3 SOP: External IRBs (HRP-092)
- 6.4 SOP: Northwestern University Serving as the IRB of Record (HRP-093)
- 6.5 WORKSHEET: Authorization Agreement Review (HRP-1801)
- 6.6 WORKSHEET: Communication and Responsibilities (HRP-830)
- 6.7 FORM: Institutional Profile (HRP-815)
- 6.8 TEMPLATE: Authorization Agreement (Northwestern University IRB\_NOT IRB of Record)
- 6.9 TEMPLATE: Authorization Agreement (Northwestern University IRB\_ IRB of Record)

## 7 REFERENCES

- 7.1 NOT-OD-16-094: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research
- 7.2 SMART IRB Agreement: <https://smartirb.org/agreement/>