



SOP: Institutional Profile Management

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1 PURPOSE

- 1.1 This procedure establishes the process to manage Institutional Profiles.
- 1.2 The process begins when a Northwestern University IRB staff member has identified an external IRB from another institution/organization, for a potential Authorization Agreement as defined in “SOP: Establishing Authorization Agreements (HRP-801)”.
- 1.3 The process ends when the Authorization Agreement is fully executed and the Institutional Profile has been completed.

2 PREVIOUS VERSION

- 2.1 None.

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)”.
 - 3.1.3 The Institutional Profile is completed during the negotiation process of an Authorization Agreement.

4 RESPONSIBILITIES

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

5 PROCEDURE

- 5.1 Upon receipt of a request to execute an Authorization Agreement with an external institution/organization, the IRB Office staff member will complete the following in eIRB+:
 - 5.1.1 Update “GENERAL DOCUMENT: Institutional Profile (HRP-815)” and “WORKBOOK: Institutional Profiles (HRP-861)” for the external institution/organization per the information in the Authorization Agreement.
- 5.2 Upon completing the process outlined in “SOP: External IRBs (HRP-092)” or “SOP: Northwestern University serving as the IRB of Record (HRP-093)”, the Institutional Profile should be updated to indicate the following:
 - 5.2.1 The external institution/organization is eligible to be a participating site on a multi-site study.
 - 5.2.2 The external institution/organization is eligible to be a single IRB of record in a multi-site study.
 - 5.2.3 Reports of new information should be routed to the external institution/organization for review when they are the sIRB.
- 5.3 The fully executed Authorization Agreement should be uploaded into the Institutional Profile section. Once the above information has been identified, the Institutional Profile is considered complete.

6 MATERIALS

- 6.1 GENERAL DOCUMENT: Human Research Protection Program Plan (HRP-101)
- 6.2 SOP: External IRBs (HRP-092)



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- 6.3 SOP: Northwestern University Serving as the IRB of Record (HRP-093)
- 6.4 SOP: Establishing Authorization Agreements (HRP-801)
- 6.5 GENERAL DOCUMENT: Institutional Profile (HRP-815)
- 6.6 WORKBOOK: Institutional Profile (HRP-861)

7 REFERENCES

- 7.1 None