



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)”.
- 3.2 For cases where the Northwestern University IRB will cede review to an external Single IRB or IRB of Record, an Institutional Profile will be verified or created in eIRB+.

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 cede IRB Review to an external IRB, the IRB Office staff member will complete the following in eIRB+:
 - 5.1.1 Verify whether an Institutional Profile (HRP-815) has already been created in eIRB+ and accurately reflects the institution intended to serve as the IRB of Record.
 - 5.1.2 If an institutional profile for the proposed IRB of Record has not yet been created, or the profile is not up to date, the staff member will create or update the Institutional Profile (HRP-815) in eIRB+. The institutional profile should be completed per the information in the Authorization Agreement or with information provided by the external IRB or their HRPP.
- 5.2 The Institutional Profile should be created or updated to indicate the following:
 - 5.2.1 The external IRB name, FWA number, IORG number, quality control mechanism, and other key information.
 - 5.2.2 The external IRB is or is not eligible to be a participating site for multi-site research.
 - 5.2.3 The external IRB is eligible to be an IRB of record for multi-site research.
 - 5.2.4 Reports of new information will not be routed to the external institution/organization for review via eIRB+ when they are serving as the IRB of Record. Any applicable reports of new information will be routed to the external institution/organization per preferences expressed in either the Authorization Agreement, Local Context Form, or Institutional Communication Plan.
- 5.3 Prior to the acknowledgment of any external IRB submission in eIRB+, the Institutional Profile for the IRB of Record will be correctly linked to the individual study submission. This is achieved via the designation of that institution on the ‘External IRB’ page of the STU submission.



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6 MATERIALS

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

7 REFERENCES

- 7.1 None