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)
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