



SOP: Institutional Profile Management

1 PURPOSE

- 1.1 The purpose of this process is to manage Institutional Profiles.
- 1.2 This process begins when this institution receives new or updated information from another institution/organization that impacts the content of the Institutional Profile.
- 1.3 This process ends when updated information has been communicated to appropriate parties.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 Any substantive changes to an Institutional Profile must be the result of an amended Authorization Agreement. Any non-substantive changes, e.g., contact information updates, do not require an amended Authorization Agreement.
- 3.2 The institution may leverage an existing Institutional Profile to collect information requested in HRP-861 - WORKBOOK - Institutional Profiles. For example, Institutional Profiles created for iREX or the SMART IRB platform are acceptable.

4 RESPONSIBILITIES

- 4.1 The IRB Reliance Coordinator or Director generally carries out these procedures.

5 PROCEDURE

- 5.1 Update the saved HRP-815 - FORM - Institutional Profile for the institution/organization with the amended Authorization Agreement.
- 5.2 Update HRP-861 - WORKBOOK - Institutional Profiles with the information you included in HRP-815 - FORM - Institutional Profile.
- 5.3 File the updated HRP-815 - FORM - Institutional Profile with the amended Authorization Agreement.
- 5.4 Determine whether the updates impact any existing studies. If so, develop a plan for how to address the impact.
- 5.5 Communicate these updates and any plans to address impacts to appropriate parties as needed.

6 MATERIALS

- 6.1 HRP-815 - FORM - Institutional Profile
- 6.2 HRP-861 - WORKBOOK - Institutional Profiles

7 REFERENCES

- 7.1 None