

SOP: Institutional Profile Management

NUMBER	DATE	PAGE
13.005 (HRP-802)	11/18/2024	1 of 1

1 PURPOSE

- 1.1 The purpose of this process is to manage changes to Institutional Profiles.
- 1.2 This process begins when this institution receives 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 the appropriate parties.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 05/04/2024.

3 POLICY

- 3.1 Any substantive changes to an Institutional Profile must be the result of an amended Authorization Agreement approved by the IRB as a Modification. Any non-substantive changes, e.g., contact information updates do not require an amended Authorization Agreement.

4 RESPONSIBILITIES

- 4.1 The Reliance Administrator generally carries out these procedures.

5 PROCEDURE

- 5.1 Update the saved 13.304 - FORM - Relying Site Local Considerations for the institution/organization with the amended Authorization Agreement.
- 5.2 Update Institutional Profiles Folder in One-Drive with the information you included in 13.304 – FORM - Relying Site Local Considerations
- 5.3 File the updated 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 13.304 – FORM - Relying Site Local Considerations.
- 6.2 One Drive Institutional Profiles Folder.

7 REFERENCES

- 7.1 None.