

**SOP: Site Validation**

NUMBER

DATE

PAGE

13.003 (HRP-803)

11/22/24

1 of 1

**1 PURPOSE**

- 1.1 The purpose of this process is to validate that a particular study meets the criteria either for this institution to serve as the IRB of record or for this institution to rely on an external IRB.
- 1.2 This process begins when IRB staff identify a submission with a participating site.
- 1.3 This process ends when the study has been validated as meeting the criteria or not.

**2 REVISIONS FROM PREVIOUS VERSION**

- 2.1 2/1/21.

**3 POLICY**

- 3.1 None.

**4 RESPONSIBILITIES**

- 4.1 The Reliance Administrator generally carries out these procedures.

**5 PROCEDURE**

- 5.1 IRB staff notify Reliance Administrator after completion of Pre-Review procedures of applicable study submissions. See 13.002 (HRP-804) – SOP - Site Pre-Review.
- 5.2 If the item is a request for this IRB to review for another participating site, do the following:
  - 5.2.1 Check One Drive Institutional Profiles Folder to determine whether an existing Authorization Agreement covers the study activities.
  - 5.2.2 Determine whether to execute an Authorization Agreement.
    - 5.2.2.1 If so, follow 13.007 (HRP-801) - SOP - Establishing Authorization Agreements.
    - 5.2.2.2 Obtain signatures to consummate the Authorization Agreement.
    - 5.2.2.3 Provide an executed Authorization Agreement to the site.
    - 5.2.2.4 When, applicable, inform the requestor that this IRB will not serve as the IRB or record for that site.
- 5.3 If the item is a request for this institution to rely on another IRB for review, do the following:
  - 5.3.1 Check One Drive Institutional Profiles Folder to determine whether an existing Authorization Agreement covers the study activities.
  - 5.3.2 Determine whether to execute an Authorization Agreement.
    - 5.3.2.1 If so, follow 13.007 (HRP-801) – SOP - Establishing Authorization Agreements.
    - 5.3.2.2 Obtain signatures to consummate the Authorization Agreement.
    - 5.3.2.3 Ensure that the IRB Office has received an executed Authorization Agreement. When applicable, inform the requestor that this IRB will not rely on the other IRB.

**6 MATERIALS**

- 6.1 13.002 (HRP-804) – SOP – Site Pre-Review.
- 6.2 13.007 (HRP-801) - SOP - Establishing Authorization Agreements.
- 6.3 OneDrive Institutional Profiles Folder.

**7 REFERENCES**

- 7.1 None.