

SOP: External IRB Post-Review

1 PURPOSE

- 1.1 The purpose of this process is to conduct post-review for submissions where this institution is being asked to rely on an external IRB.
- 1.2 This process begins when a request to rely oversight has been submitted and pre-review has been completed.
- 1.3 This process ends when all correspondence related to IRB determinations and actions have been sent and additional tasks have been completed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 POLICY

- 3.1 None.

4 RESPONSIBILITIES

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

5 PROCEDURE

- 5.1 For studies where IRB oversight has been ceded to an external IRB:
 - 5.1.1 Execute the "Record sIRB Decision" activity and complete the Smartform with the information in the external IRB approval letter. Upload the external IRB determination letter in the designated space for "External IRB Approval Letter" if not already attached under "Other Attachments" in the study application.
 - 5.1.2 Execute the "Finalize Documents" activity if necessary.
 - 5.1.3 Execute the "Prepare Letter" activity to generate and edit HRP-857 - LETTER - Acknowledge External IRB.
 - 5.1.4 Execute the "Send Letter" activity.

6 MATERIALS

- 6.1 HRP-857 - LETTER - Acknowledge External IRB

7 REFERENCES

- 7.1 None