



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 cede oversight has been submitted and pre-review as well as any required ancillary reviews have 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 IRB Reliance Coordinator or IRB manager generally carry out these procedures.

5 PROCEDURE

- 5.1 For studies where IRB oversight has been ceded to an external IRB:
 - 5.1.1 Use HRP-857 - Letter - Acknowledge External IRB and send the acknowledgement to the local study team.
 - 5.1.2 File the external IRB's determination letter and all communications in the study file.

6 MATERIALS

- 6.1 HRP-857 - LETTER - Acknowledge External IRB

7 REFERENCES

- 7.1 None