

SOP: Site Updates

NUMBER

DATE

PAGE

13.004 (HRP-805)

11/21/24

1 of 1

1 PURPOSE

- 1.1 The purpose of this process is to ensure that the relying institution is made aware of updates approved by the external IRB.
- 1.2 This process begins when the local site submits newly approved materials from the external IRB.
- 1.3 This process ends when an external IRB submission has been updated.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None.

3 POLICY

- 3.1 An investigator relying on an external IRB must update the study if any of the following changes are approved by the external IRB:
- 3.2 Changes in Principal Investigator and/or study team personnel.
- 3.3 Changes in research sites under Rutgers University PI's leadership.
- 3.4 Change in research funding.
- 3.5 Changes to research design/procedure that resulted in changes to study documents.
- 3.6 A reportable event that resulted in changes to study documents.
- 3.7 The Continuing Review approval letter must be provided to the IRB Office in accordance with the procedure/instructions listed on the IRB website.

4 RESPONSIBILITIES

- 4.1 The Reliance Administrator generally carries out these procedures.

5 PROCEDURE

- 5.1 If the updates are satisfactory, accept them.
- 5.2 If the updates are not satisfactory, request clarification.
 - 5.2.1 When the investigator responds to the clarification request, confirm that the request clarifications were made.
 - 5.2.2 If the clarifications are satisfactory, accept them.
- 5.3 Acknowledge External IRB Update

6 MATERIALS

- 6.1 Acknowledge External IRB Update.

7 REFERENCES

- 7.1 None.