



SOP: External IRB Updates

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 or when the local investigator makes changes at the site level.
- 1.2 This process begins when the local site investigator submits newly approved materials from the external IRB or when the local investigator submits local site changes.
- 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 with changes approved by the external IRB, including providing notification of Continuing Review approval.
- 3.2 Any changes approved by the external IRB that in the opinion of the principal investigator indicate increased risk to participants and/or increased administrative burden on CCH resources must be submitted to the CCH IRB using HRP-213 - FORM - Modification.
- 3.3 Notification of Continuing Review approval must be submitted to the CCH IRB using HRP-215 – FORM – Annual Check In. The PI must inform the IRB when the study has concluded using HRP-212 – FORM – Continuing Review/Closure in IRBManager.
- 3.4 If changes are made to local site documents, including local consent documents, recruitment materials, or local study team members the investigator must update the site record using HRP-213 - FORM - Modification.

4 RESPONSIBILITIES

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

5 PROCEDURE

- 5.1 If the item includes updates to the local site (HRP-213 - FORM - Modification) for modifications to study team members or other parts of the site, review the updates in accordance with the roles and responsibilities of your institution as outlined in HRP-830 - WORKSHEET - Communication and Responsibilities.
 - 5.1.1 If the item includes other updates or are not satisfactory:
 - 5.1.1.1 Request clarifications from the Investigator.
 - 5.1.1.2 When the investigator responds to the clarifications request, confirm that the requested clarifications were made.
 - 5.1.2 When all updates to the local site are satisfactory, accept them.

5.1.3 Send HRP-859 - TEMPLATE LETTER - Acknowledge External IRB Update.

5.2 If the item is an update to the overall study (HRP-213 - FORM - Modification) including changes to funding, study scope, or overall study related documents and template, review the updates in accordance with the roles and responsibilities of your institution as outlined in HRP-830 - WORKSHEET - Communication and Responsibilities.

5.2.1 If the changes are unsatisfactory or require additional changes:

5.2.1.1 Contact the Investigator and request the changes needed.

5.2.1.2 When the investigator responds to the request, confirm that the requested changes were made.

5.2.2 When all updates to the overall study are satisfactory, accept them.

5.2.3 Send HRP-859 - TEMPLATE LETTER - Acknowledge External IRB Update.

6 MATERIALS

6.1 HRP-212 - FORM - Continuing Review/Closure

6.2 HRP-213 - FORM - Modification

6.3 HRP-215 - FORM - Annual Check In

6.4 HRP-830 - WORKSHEET - Communication and Responsibilities

6.5 HRP-859 - TEMPLATE LETTER - Acknowledge External IRB Update

7 REFERENCES

7.1 None.