



SOP: External IRB Updates				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
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**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 investigator 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 GUIDING PRINCIPLES**

- 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, using the “Update Study Details” activity.  
UM does not require continuing reports for external IRB studies. The study team must monitor the ‘Last day of Approval period’ and update as appropriate if needed by them for record keeping purposes.
- 3.2 If changes are made to local site documents on an externally reviewed multi-site study, including local consent documents, recruitment materials, or local study team members the investigator must update the site using the “Create Site Modification” activity.

**4 RESPONSIBILITIES**

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

**5 PROCEDURE**

- 5.1 If the item includes updates to the local site (Site Modification for 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 and are not satisfactory:
    - 5.1.1.1 Request clarifications from the Investigator by executing the “Request Pre-Review Clarification” Activity.
    - 5.1.1.2 When the investigator responds to the clarification request, confirm that the requested clarifications were made.
  - 5.1.2 When all updates to the local site are satisfactory, accept them by executing the “Accept Site Updates” activity.
  - 5.1.3 When all updates to the local site have been accepted, execute the “Record sIRB Decision” activity and complete the SmartForm, indicating whether or not documents need to be finalized or a letter needs to be sent.
  - 5.1.4 If applicable, execute the “Finalize Documents” and then the “Send Letter” activities.
- 5.2 If the item is an update to the overall study (Update to Study Details for funding, study scope, or 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.

**6 MATERIALS**

- 6.1 HRP-830 - WORKSHEET - Communication and Responsibilities
- 6.2 HRP-859 - TEMPLATE LETTER - Acknowledge External IRB Update

**7 REFERENCES**

- 7.1 None.