University of New Mexico Health Sciences Center
Human Research Protections Office

Title: External IRB Site Updates
SOP #: HRP-805
Revision #: 0
Effective Date

Reviewed/Recommended for Approval: Thomas Byrd, M.D., Executive Chair HRRC
Approved: Richard Larson, MD PhD Executive Vice Chancellor for HSC and Vice Chancellor for Research
Date:

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 (WIRB, NCI-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 acknowledged by the HRRC.

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.

4 RESPONSIBILITIES
4.1 The HRPO Staff/Reliance Coordinator 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.
   5.2.3 No Letter will be sent to the pSite – an automatic email notification will be generated notifying the study team the updates have been acknowledged.

6 MATERIALS
6.1 None.

7 REFERENCES
7.1 None.