1. PURPOSE
   1. The purpose of this process is to ensure that the relying institution is made aware of updates approved by the external IRB.
   2. This process begins when the local site submits newly approved materials from the external IRB.
   3. This process ends when an external IRB submission has been updated.
2. REVISIONS FROM PREVIOUS VERSION
   1. None.
3. POLICY
   1. An investigator relying on an external IRB must update the study if any of the following changes are approved by the external IRB:
   2. Changes in Principal Investigator and/or study team personnel.
   3. Changes in research sites under Rutgers University PI’s leadership.
   4. Change in research funding.
   5. Changes to research design/procedure that resulted in changes to study documents.
   6. A reportable event that resulted in changes to study documents.
   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
   1. The Reliance Administrator generally carries out these procedures.
5. PROCEDURE
   1. If the updates are satisfactory, accept them.
   2. If the updates are not satisfactory, request clarification.
      1. When the investigator responds to the clarification request, confirm that the request clarifications were made.
      2. If the clarifications are satisfactory, accept them.
   3. Acknowledge External IRB Update
6. MATERIALS
   1. Acknowledge External IRB Update
7. REFERENCES
   1. None.