1. PURPOSE
   1. The purpose of this process is to conduct pre-review for a site submission prior to materials being sent to the IRB of record.
   2. This process begins when a site submits materials for pre-review.
   3. This process ends when a site submission is sent to the IRB of record.
2. REVISIONS FROM PREVIOUS VERSION
   1. None.
3. POLICY
   1. None.
4. RESPONSIBILITIES
   1. The Reliance Coordinator generally carries out these procedures.
5. PROCEDURE
   1. Check the submission materials for completeness. This includes:
      1. “FORM: Basic Site Information (HRP-811).”
      2. Site documents submitted for review.
      3. Consult “WORKSHEET: Pre-Review (HRP-308)” to prompt for any other items relevant for this institution. Use “CHECKLIST: Pre-Review (HRP-401)” to document any missing materials.
      4. Send a request for any missing materials to the site contact.
   2. Confirm that all local issues have been resolved.
      1. If not, send a request to resolve any local issues.
   3. Once the submission is ready to be sent to the IRB of record, notify the local investigator of permission to seek IRB approval using “LETTER: Acknowledge External IRB Review (HRP-857).”
6. MATERIALS
   1. FORM: Basic Site Information (HRP-811)
   2. WORKSHEET: Pre-Review (HRP-308)
   3. CHECKLIST: Pre-Review (HRP-401)
   4. LETTER: Acknowledge External IRB (HRP-857)
7. REFERENCES
   1. None.