1 PURPOSE

1.1 The purpose of this process is to conduct pre-review for a site submission.

1.2 This process begins when a site submits materials for pre-review.

1.3 This process ends when a site submission is approved by the IRB of record.

2 REVISIONS FROM PREVIOUS VERSION

2.1 12/01/2019.

3 POLICY

3.1 None.

4 RESPONSIBILITIES

4.1 The Reliance Administrator generally carries out these procedures.

5 PROCEDURE

5.1 Check the submission materials for completeness. This includes:

5.1.1 eIRB+ Application.

5.1.2 Site documents submitted for review in accordance with the Authorization Agreement and/ contract. Consult 3.205 (HRP-308) - WORKSHEET: Pre-Review to prompt for any other items relevant for this institution. Use 3.102 (HRP-401) - CHECKLIST: Pre-Review to document any missing materials.

5.1.3 Send a request for any missing materials to the site contact.

5.2 Confirm that all ancillary committee approvals and training requirements have been obtained and are current (e.g., Conflict of Interest, CITI training, Ancillary reviews (SRB, Radiation, IBC), Performance site agreements (RUG, OCRA, UBHC)).

5.2.1 If not, send a request to resolve any local issues.

5.3 Once the submission is ready to be sent to the IRB of record, notify the local investigator of permission to seek IRB approval.

6 MATERIALS

6.1 eIRB+ Application.

6.2 3.102 (HRP-401) - CHECKLIST: Pre-Review.

6.3 3.205 (HRP-308) - WORKSHEET: Pre-Review.

6.4 3.303 LETTER: Acknowledge External IRB (eIRB+).

7 REFERENCES

7.1 None.