1 PURPOSE
1.1 The purpose of this process is to conduct pre-review for a site submission prior to materials being sent to the IRB of record.
1.2 This process begins when a site submits sIRB consent with local context and other study materials for pre-review.
1.3 This process ends when a site submission is sent to the IRB of record.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None

3 POLICY
3.1 None.

4 RESPONSIBILITIES
4.1 The HRPO Staff generally carries out these procedures.

5 PROCEDURE
5.1 Check the submission materials for completeness. This includes:
  5.1.1 Site documents submitted for review.
  5.1.2 Use “CHECKLIST: Pre-Review (HRP-401a)” to document any missing materials.
  5.1.3 Send a request for any missing materials or for revisions of submitted materials to the site contact.
5.2 Confirm that all local issues have been resolved.
5.3 Applicable Ancillary Reviews are complete
5.4 Applicable COIs are complete
  5.4.1 If not, send a request to resolve any local issues.
5.5 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: HRRC Cedes to Site (HRP-857).” The PI is notified of approval to seek external IRB approval by HRPO Staff. When the Huron Exchange is active the submission will be automatically routed to the external IRB for review.

6 MATERIALS
6.1 CHECKLIST: Pre-Review (HRP-401a)
6.2 LETTER: HRRC Cedes to Site (HRP-857)

7 REFERENCES
7.1 None.