1 PURPOSE
1.1 The purpose of this process is to validate that a particular study meets the criteria either for this institution to serve as the IRB of record or for this institution to rely on an external IRB.
1.2 This process begins when IRB staff identify a submission with a participating site.
1.3 This process ends when the study has been validated as meeting the criteria or not.

2 REVISIONS FROM PREVIOUS VERSION
2.1 None.

3 POLICY
3.1 None.

4 RESPONSIBILITIES
4.1 HSRO Staff generally carries out these procedures.

5 PROCEDURE
5.1 If the item is a request for this IRB to review for another participating site, do the following:
   5.1.1 Identify the site.
   5.1.2 Determine whether the site has an Institutional Profile
   5.1.3 Determine whether the site has an Authorization Agreement that covers the study activities.
      5.1.3.1 If so, proceed with Pre-Review.
      5.1.3.2 If not, determine whether or not you will execute an Authorization Agreement.
         5.1.3.2.1 If so, follow “SOP: Establishing Authorization Agreements (HRP-801).”
         5.1.3.2.1.1 Proceed with Pre-Review when the agreement has been executed.
         5.1.3.2.1.2 Inform the site that this institution will serve as the IRB of record for the site. Use “LETTER: Invitation Decision (HRP-851),” or equivalent, to inform the site that this IRB will serve as its IRB of record.
      5.1.3.2.2 If not, inform the requestor that this IRB will not serve as the IRB of record for that site.

5.2 If the item is a request for this institution to rely on another IRB for review, do the following:
   5.2.1 Identify the IRB.
   5.2.2 Determine whether an existing Authorization Agreement covers the study activities.
      5.2.2.1 If so, proceed with Pre-Review.
      5.2.2.2 If not, determine whether or not you will execute an Authorization Agreement.
         5.2.2.2.1 If so, follow “SOP: Establishing Authorization Agreements (HRP-801).” Proceed with Pre-Review when the agreement has been executed.
         5.2.2.2.2 If not, inform the requestor that this institution will not rely on the other IRB.

6 MATERIALS
6.1 SOP: Establishing Authorization Agreements (HRP-801)
6.2 LETTER: Invitation Decision (HRP-851)

7 REFERENCES
7.1 None.
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