



SOP: Site Validation					
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HRP-803	1/19/18	1	E. Bital	K. Hirani	1 of 2

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.

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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.

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- 5.1.3.1 If so, proceed with Pre-Review.

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- 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.

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- 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.

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- 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.

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- 5.2.2.1 If so, proceed with Pre-Review.

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- 5.2.2.2 If not, determine whether or not you will execute an Authorization Agreement.

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- 5.2.2.2.1 If so, follow "SOP: Establishing Authorization Agreements (HRP-801)." Proceed with Pre-Review when the agreement has been executed.

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- 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)

Deleted: WORKBOOK: Institutional Profiles (HRP-861)

7 REFERENCES

- 7.1 None.

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