SOP: Reliance Pre-Review				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
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1 PURPOSE

1.1 The purpose of this process is to conduct pre-review for submissions where this institution is being asked to rely on an external IRB, or where this institution is asked to assume IRB oversight of external Participating Sites (pSite).

1.2 This process begins when a request to rely or cede oversight is submitted for pre-review.

1.3 This process ends when reliance on the external IRB is confirmed or this institution confirms it will assume oversight for external Participating Sites (pSite).

2 REVISIONS FROM PREVIOUS VERSION

2.1 None.

3 POLICY

3.1 Any institution located in the United States that is engaged in federally-funded cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States. The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or proposed by the lead institution subject to the acceptance of the Federal department or agency supporting the research.

3.2 An NIH funded study being conducted at more than one U.S. site involving non-exempt human subjects research may be subject to the NIH Single IRB policy and/or the revised Common Rule cooperative research provision (§46.114).

3.3 Studies utilizing the NCI CIRB may be submitted directly to NCI CIRB without first requesting reliance.

4 RESPONSIBILITIES

4.1 The IRB staff members assigned to Reliance duties generally carry out these procedures.

5 PROCEDURE

5.1 If the item is a submission of approval documents for a study already reviewed by and approved by an external IRB[1].

5.1.1 Check the submission materials for completeness. This includes:

5.1.1.1 The Basic Information SmartForm and External IRB SmartForm pages.

5.1.1.2 Study related documents, if this is a study relying on an external IRB.

5.1.1.3 Local site documents, if this is a study relying on an external IRB.

5.1.2 Use HRP-309 - WORKSHEET - Ancillary Review Matrix to identify any ancillary reviews that are needed before reliance can be confirmed.

5.1.3 Review for local context to determine whether local requirements are satisfied:

5.1.3.1 If consent and/or assent template(s) were provided by the Sponsor or lead site, confirm that the local consent document is uploaded to the Local Site Documents page and includes the required local language.

5.1.3.2 If recruitment templates were provided by the Sponsor or lead site, confirm that the revised local versions are uploaded to the Local Site Documents page and aligns with local recruitment policies.

5.1.4 Note any missing materials in HRP-401A - CHECKLIST - Ceding Pre-Review and return the submission to the study team.

[1] This includes, per institutional policy, external IRB studies for which local confirmation of reliance is not required prior to submission to the IRB of record. This would also include NCI CIRB submissions.

5.1.5 Execute the "Request Pre-Review Clarification" activity to send a request for any missing materials to the local study team.

5.1.6 Once all required ancillary reviews and local requirements are complete, execute the "Confirm Reliance" activity.

5.1.7 Refer to HRP-804 - SOP - External IRB Post-Review.

5.2 If the item is a request for this institution to rely on another IRB[2]:

5.2.1 Identify the external IRB.

5.2.2 Consult HRP-861 - WORKBOOK - Institutional Profiles to determine whether there is sufficient information about the external IRB to confirm reliance.

5.2.3 If not, follow HRP-801 - SOP - Establishing Authorization Agreements to collect the information needed to confirm reliance and add to HRP-861 - WORKBOOK - Institutional Profiles.

5.2.4 Refer to the "Reliance Agreements" folder in the IRB Shared Drive and/or the SMART IRB online platform. Determine whether an existing Authorization Agreement covers the study activities for the external IRB identified.

5.2.5 If not, follow HRP-801 - SOP - Establishing Authorization Agreements to collect the information needed to confirm reliance and create a new Institutional Profile.

5.2.6 Once the required information is obtained and the necessary agreements are in place, check the submission materials for completeness. This includes:

5.2.6.1 The Basic Information SmartForm and External IRB SmartForm pages.

5.2.6.2 Study related documents, if this is a study relying on an external IRB.

5.2.6.3 Local site documents, if this is a study relying on an external IRB.

5.2.7 Use 309 - WORKSHEET - Ancillary Review Matrix to identify the ancillary reviews that must be completed prior to submission to an external IRB.

5.2.8 Review for local context to determine whether local requirements are satisfied:

5.2.8.1 If consent and/or assent template(s) were provided by the Sponsor or lead site, confirm that the local consent document is uploaded to the Local Site Documents page and includes the required local language.

5.2.8.2 If recruitment templates were provided by the Sponsor or lead site, confirm that the revised local versions are uploaded to the Local Site Documents page and aligns with local recruitment policies.

5.2.9 Note any missing materials in HRP-401A - CHECKLIST – Ceding Pre-Review and return the submission to the study team.

5.2.10 Execute the "Request Pre-Review Clarification" activity to send a request for any missing materials to the local study team.

5.2.11 Once all required ancillary reviews and local requirements are complete, execute the "Confirm Reliance" activity.

5.2.12 Refer to HRP-804 - SOP - External IRB Post-Review.

5.3 If the item is a request for this institution to serve as the single IRB of record (sIRB) for an external pSite:

5.3.1 Review the submission and identify all pSites (Note: pSites can only be approved after the approval of the main study).

[2] This includes, per institutional policy, external IRB studies for which local confirmation of reliance is required prior to submission to the IRB of record.

5.3.2 Refer to the “Reliance Agreements” folder in the IRB Shared Drive and/or the SMART IRB online platform to determine whether an existing Authorization Agreement covers the study activities for each pSite identified.

5.3.3 If not, follow HRP-801 - SOP - Establishing Authorization Agreements to collect the information needed to confirm reliance and add to HRP-861 - WORKBOOK - Institutional Profiles.

5.3.4 Notify the assigned IRB coordinator that this institution will serve as the sIRB for each pSite and can proceed with Pre-Review using HRP-021 - SOP - Pre-Review.

5.3.5 Once all the information is complete and the authorization agreement has been executed, execute the “Submit invitation Decision” activity to notify the pSite that this IRB will serve as the IRB of Record for their participation in the study.

5.3.6 Re-assign the submission to an IRB Coordinator to proceed with Pre-Review.

6 MATERIALS

6.1 HRP-031 - SOP - Non-Committee Review Preparation
6.2 HRP-401A – CHECKLIST - Ceding Pre-Review
6.3 HRP-309 - WORKSHEET - Ancillary Review Matrix
6.4 HRP-801 - SOP - Establishing Authorization Agreements
6.5 HRP-804 - SOP - External IRB Post-Review
6.6 HRP-861 - WORKBOOK - Institutional Profiles

7 REFERENCES

7.1 None.

8 PREVIOUS VERSIONS