HRP-803 | 3/15/2024

SOP: Reliance Pre-Review

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.

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.

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 Reliance Coordinator or IRB staff and designated IRB member 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[i].

5.1.1 IRB Reliance Coordinator or IRB staff check the submission materials for completeness. This includes:

5.1.1.1 HRP-211 - FORM - Basic Site Information.

5.1.1.2 Study related documents, if this is a multi-site or collaborative study relying on an external IRB.

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

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

5.1.3 If the submission is complete, assign to IRB member for administrative review. The IRB member will review for local context to determine whether local requirements are satisfied. If any requirements are not met, IRB staff will contact the investigator to resolve.

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

5.1.5 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[ii]:

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 Once the required information is obtained and the necessary agreements are in place, IRB Reliance Coordinator or IRB staff check the submission materials for completeness. This includes:

5.2.4.1 HRP-211 - FORM - Basic Site Information.

5.2.4.2 Study related documents, if this is a multi-site or collaborative study relying on an external IRB.

5.2.4.3 Local site documents, if this is a single-site study relying on an external IRB.

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

5.2.6 If the submission is complete, assign to IRB member for administrative review. The IRB member will review for local context to determine whether local requirements are satisfied. If any requirements are not met, IRB staff will contact the investigator to resolve.

5.2.7 Consult HRP-309 - WORKSHEET - Ancillary Review Matrix to identify any additional ancillary reviews that must be completed prior to submission to an external IRB.

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

6 MATERIALS

6.1 HRP-211 - FORM – Basic Site Information

6.2 HRP-309 - WORKSHEET - Ancillary Review Matrix

6.3 HRP-401 - CHECKLIST - Pre-Review

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.

[i] 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.

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