SOP: Review Request to Rely on an External IRB

1 PURPOSE

1.1 This procedure establishes the process to ensure the criteria for this Institution to rely on an external IRB for review and oversight of non-exempt human research have been met.

1.2 This process begins when a study team submits a request to rely on an external IRB.

1.3 This process ends when the request to rely on an external IRB has been approved or declined.

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 POLICY

3.1 The IO/OO or their designee has the authority to determine what IRBs the Institution will rely upon, as well as approve and rescind authorization agreements for IRBs.

3.2 Reliance on an external IRB requires an Authorization Agreement and an active local Institutional Profile, as well as a local review for compliance with local policies of the Institution.

4 RESPONSIBILITIES

4.1 The Reliance Coordinator or IRB staff carry out these procedures.

5 PROCEDURE

5.1 Click on the Institutional Profile area in IRB system and determine if the external IRB has an active profile.

5.1.1 If there is an active profile and the IRB is not required to approve each individual request to rely for this external IRB (e.g. NCI CIRB), go to Section 5.2.2.

5.1.2 If there is not an active profile OR the IRB is required to approve each individual request to rely for this external IRB, proceed to next section.

5.2 Using HRP-832 - PI WORKSHEET - Criteria for Relying on an External IRB, determine if the study is eligible to rely on an external IRB of record.

5.2.1 If the study does not meet the criteria for reliance on an external IRB:

5.2.1.1 Execute the Confirm Reliance Activity.

5.2.1.2 Indicate NO to the question #3 “Confirm reliance on the single IRB of record?”

5.2.1.2.1 Manually prepare and send HRP-856- Reliance Determination Decline to Rely to communicate the determination to the Investigator.

5.2.1.2.2 If the Investigator chooses to submit a response to the IRB regarding the determination, proceed with step 5.1 above.

5.2.2 If the study is eligible to rely on an external IRB of record:

5.2.2.1 Determine if a valid authorization agreement is in the Institutional Profile.

5.2.2.1.1 If not, follow HRP-801 - SOP - Establishing Agreements to create a new authorization agreement.

5.2.2.2 Confirm that all local requirements and ancillary reviews are complete.

5.2.2.2.1 Human Subjects Training is complete.

5.2.2.2.2 Conflict of Interest management plan is in place when applicable and will be provided to IRB of Record.

5.2.2.2.3 Written consent to be used at this institution includes institutionally required language where applicable.
5.2.2.2.4 HIPAA Authorization language is provided as separate document to be used at this institution when applicable to the study.
5.2.2.2.5 Refer to the Institutional Profile or authorization agreement to determine institutional responsibilities.
5.2.2.2.6 Use HRP-441 PI WORKSHEET - HIPAA Waiver of Authorization when applicable and this institution will serve as Privacy Board.
5.2.2.2.7 Use HRP-064 -SOP- NIH GDS Institutional Certification and HRP-332 PI WORKSHEET NIH GDS Institutional Certification when applicable and this institution is responsible for certification.
5.2.2.2.8 All relevant local ancillary review requirements have been met or are in progress in accordance with HRP-309 - WORKSHEET - Ancillary Review.

5.2.2.3 If any institutional requirements are not met, execute the "Request Pre-Review Clarification" activity from the investigator.
5.2.2.4 Offer the investigator the opportunity to update the submission.
5.2.2.5 Execute the Confirm Reliance Activity:
5.2.2.5.1 Indicate YES or NO to the question "Confirm reliance on the single IRB of record?"
5.2.2.5.2 If you indicated YES and the investigator does not yet have external IRB approved documents, and your institution requires these be provided, leave the study in "Pending sIRB Review" state and wait for the Investigator to log a comment with IRB approved documents. Communicate this requirement to the Investigator via the "Correspond with sIRB" activity.
5.2.2.6 If the investigator already uploaded external IRB approved documents for this site (e.g., NCI CIRB), execute the "Record sIRB Decision" activity and complete any information required by the local IRB.
5.2.2.6.1 Indicate NO to the question "Do you need to finalize documents or send a letter" unless finalizing documents and/or sending a letter is required. This moves the study to the Review Complete state.
5.2.2.6.2 Indicate YES if finalizing documents and/or sending a letter is required. This will move the study to the Post Review state.
5.2.2.7 Refer to HRP-804 - SOP - External IRB Post-Review.

6 MATERIALS

6.1 HRP-064 -SOP- NIH GDS Institutional Certification
6.2 HRP-309 - WORKSHEET - Ancillary Review Matrix
6.3 HRP-332 - WORKSHEET - NIH GDS Institutional Certification
6.4 HRP-441 - WORKSHEET - HIPAA Waiver of Authorization
6.5 HRP-801 - SOP - Establishing Agreements
6.6 HRP-804 - SOP - External IRB Post-Review
6.7 HRP-815 - FORM - Institutional Profile
6.8 HRP-832 - PI WORKSHEET - Considerations for Ceding IRB Review
6.9 HRP-857 - LETTER - Acknowledge External IRB
6.10 HRP-856 - LETTER - Decline Reliance on an External IRB
6.11 HRP-859 - LETTER - Acknowledge External IRB Update
6.12 HRP-861 - WORKBOOK - Institutional Profiles

7 REFERENCES

7.1 SMART IRB Agreement: https://smartirb.org/agreement/

7.2 OHRP Authorization Agreement template: https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html