HRP-806 | 08/07/2025 | Author: Huron Consulting Group | Approver: HRPP Director

**SOP: Review Request to Rely on External IRB**

1. **PURPOSE**
   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.
   2. This process begins when a study team submits a request to rely on an external IRB.
   3. This process ends when the request to rely on an external IRB has been approved or declined.
2. **REVISIONS FROM PREVIOUS VERSION**
   1. Revised to align with VIRBs, revised logo and header; 8/7/25.
3. **POLICY**
   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.
   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**
   1. IRB staff carry out these procedures.
5. **PROCEDURE**
   1. Click on the Institutional Profile area in IRB system and determine if the external IRB has an active profile.
      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, Advarra, WCG), go to Section 5.2.2.
      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.
   2. Using HRP-832 - WORKSHEET - Considerations for Relying on an External IRB, determine if the study is eligible to rely on an external IRB of record.
      1. If the study does not meet the criteria for reliance on an external IRB:
         1. Execute the “Confirm Reliance” Activity.
         2. Indicate NO to the question #3, “Confirm reliance on the single IRB of record?”
            1. Prepare and send HRP-856- Reliance Determination Decline to Rely to communicate the determination to the Investigator.
            2. If the investigator chooses to submit a response to the IRB regarding the determination, proceed with step 5.1 above.
      2. If the study is eligible to rely on an external IRB of record:
         1. Determine whether an existing Authorization Agreement is in the Institutional Profile or on the VPR-IRB shared drive. If not, follow HRP-801 - SOP - Establishing Agreements to create a new Authorization Agreement.
         2. Confirm that all local requirements and ancillary reviews are complete:
            1. Reference HRP-834 - WORKSHEET - Institutional Requirements for Relying an External IRB.
            2. Refer to the Institutional Profile or Authorization Agreement to determine any additional institutional responsibilities.
         3. If any institutional requirements are not met, execute the “Request Pre-Review Clarification” activity from the investigator.
            1. Offer the investigator the opportunity to update the submission.
            2. If the investigator refuses to update the submission to meet institutional requirements:

Document any additional steps to resolve the pending request with the HRPP Director, or designee.

Advance to step 5.2.2.4, or:

Execute the “Confirm Reliance” activity and indicate NO to the question, “Confirm reliance on the single IRB of record.” Note: this will transition the submission to a final state.

Prepare and send HRP-856 - LETTER - Reliance Determination Decline to Rely to communicate the determination to the Investigator.

* + - 1. Once institutional requirements are met, execute the “Confirm Reliance” activity:
         1. In the “Confirm Reliance” activity, upload two documents under “Upload Reliance Confirmation Documents:”

HRP-857 - LETTER - Acknowledge External IRB to communicate documentation requirements to the Investigator.

Finalized Authorization Agreement.

If the study is under a master Authorization Agreement that requires additional documentation (e.g., SMART IRB letter of acknowledgement (LOA)), upload LOA or other confirmation of reliance, as provided.

Indicate YES to the question, “Confirm reliance on the single IRB of record?”

If the investigator does not yet have external IRB approved documents, leave the study in a “Pending sIRB Review” state.

* + - 1. Once the investigator has uploaded external IRB approved documents for this site:
         1. Verify the study team has uploaded the following material:

IRB approval letter,

Any applicable separate HIPAA review determinations,

IRB approved protocol

IRB approved consent, and

IRB approved recruitment materials that have VCU specific changes.

* + - * 1. Verify that VCU institutionally-required language is present in the informed consent document, as well as any other required changes from the reliance pre-review.
        2. Verify that the Reliance Coordinator logged any applicable HIPAA waivers or alterations if VCU is serving as the Privacy Board.
      1. Execute the “Record sIRB Decision” activity and complete any information made available in the approval letter. Note that all fields may not be able to be completed.
         1. Indicate NO to the question, “Do you need to finalize documents or send a letter?”
         2. Indicate YES you are ready to record the sIRB’s decision. This moves the study to the Review Complete state.
      2. For non-Massey Cancer Center industry studies, use the “Add Comment” activity to request the index number to be provided via public comment.

1. **MATERIALS**
   1. HRP-064 -SOP- NIH GDS Institutional Certification
   2. HRP-309 - WORKSHEET - Ancillary Review Matrix
   3. HRP-332 - WORKSHEET - NIH GDS Institutional Certification
   4. HRP-441 - CHECKLIST - HIPAA Waiver of Authorization
   5. HRP-801 - SOP - Establishing Agreements
   6. HRP-815 - FORM - Institutional Profile
   7. HRP-832 - WORKSHEET - Considerations for Relying on an External IRB
   8. HRP-834 - WORKSHEET - Institutional Requirements for Relying on External IRB
   9. HRP-856 - LETTER - Decline Reliance on an External IRB
   10. HRP-857 - LETTER - Acknowledge External IRB
2. **REFERENCES**
   1. SMART IRB Agreement: <https://smartirb.org/agreement/>
   2. OHRP Authorization Agreement template: <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/irb-authorization-agreement/index.html>