HRP- 834 | 08/07/2025

**WORKSHEET: Institutional Requirements for Relying on External IRB**

The purpose of this worksheet is to provide support for IRB Staff (Reliance Coordinator) screening requests to rely on an external IRB.

**Personnel Requirements**

☐ Confirm the principal investigator (PI) meets PI eligibility requirements.

☐ Determine whether the principal investigator has any lapsed studies.

☐ Confirm the Principal Investigator (and Medically or Psychologically Responsible Investigator, and Lead Student/Trainee Investigator, if applicable) have completed the required CITI training by uploading their training completion certificate with the IRB submission. The PI is responsible for ensuring all other study staff have current CITI training.

☐ If the research involves FDA oversight, confirm the principal investigator is not listed on the [FDA debarment list](https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/fda-debarment-list-drug-product-applications).

☐ If the research involves clinical activities, confirm privileges of staff conducting clinical activities.

☐ Confirm all COI Investigators have completed/updated FIRs within the last update period. Conflict of Interest management plan is in place when applicable and will be provided to IRB of Record.

**Consent Documents (Institutional Language)**

**Written consent to be used at this institution includes institutionally required language where applicable.**

See HRP-502 - TEMPLATE Consent Document for VCU template language where needed (e.g., key information section and other required Common Rule regulatory language outlined in HRP-314a - WORKSHEET - Criteria for Consent).

☐ Local contact information is included.

☐ For research involving greater than minimal risk, compensation for injury language (subject injury language) that is either VCU template language or approved by OSP or NCI CIRB boilerplate is present.

☐ For research where investigator could discover suspected child/elder abuse or a subject’s intention to injure themselves or others, mandatory reporting language is present.

☐ For research where investigator could discover a previously unknown condition that must be reported to the Health Department (e.g., Hepatitis, HIV, STDs), mandatory reporting language is present.

☐ For research where compensation is provided, collection of social security numbers for payment purposes is present (must be VCU template language where payment is directly from VCU and not sponsor).

☐ For research where VCU is responsible for contributing data to an NIH genomic data repository, disclosure of that sharing is present.

**HIPAA Authorization**

☐ NA (Study does not use or disclose protected health information (PHI) or study team is outside of the health care component.)

☐ Study activities are limited to a request for a waiver of authorization or use of limited data set.

☐ Written authorization will be obtained for activities at VCU and all required elements are present. See HRP- 330 - WORKSHEET - HIPAA Authorization.

**Privacy Board (HIPAA Waivers)**

☐ VCU is not serving as Privacy Board, or HIPAA is not applicable to this study.

☐ The external IRB is serving as the Privacy Board (as documented in the reliance agreement or HRP- 830- WORKSHEET - Communication and Responsibilities).

☐ VCU is serving as the Privacy Board (as documented in the reliance agreement or HRP- 830 - WORKSHEET - Communication and Responsibilities) for the study for purposes of review and approval of waivers of HIPAA authorization. Use HRP- 441 - CHECKLIST - HIPAA Waiver of Authorization.

**Ancillary Reviews**

Some ancillary reviews are required prior to accepting reliance on an external IRB.

See HRP-309 - WORKSHEET - Ancillary Review Matrix for more information on institutional requirements.

☐ Office of Sponsored Program memo of acceptance for subject injury language.

☐ Clinicaltrials.gov checked in SmartForm or Investigator referred to support office when unclear if applies.

☐ Information Security Office Data Management Plan for use of Category 1 Data.

☐ Institutional Biosafety Committee approval.

☐ Investigational Drug Pharmacy.

☐ Radiation Safety Committee letter.

☐ Protocol Review and Monitoring Committee (PRMC) approval.

☐ Protocol Review Oversight Committee (PROC) approval.

Other Institutional Responsibilities

☐ Use HRP-064 - SOP - NIH Genomic Data Sharing Institutional Certification and HRP-332 - WORKSHEET - NIH GDS Institutional Certification when applicable and this institution is responsible for certification.