HRP-830 | 08/07/2025

**WORKSHEET: Communication & Responsibilities**

The purpose of this worksheet is to provide support for the Reliance Coordinator, HRPP staff to identify roles and responsibilities of the IRB of Record and Participating sites as a supplement to an Authorization Agreement that does not specify this information.[[1]](#footnote-1)

1. **SCOPE**

Is this WORKSHEET being completed as a supplement to a master reliance agreement (e.g., NCI CIRB, independent IRB, reciprocal institution agreement)?

☐ Yes

☐ No

If no, complete Basic Study Information

|  |  |
| --- | --- |
| **Basic Study Information** | **Study Details** |
| IRB Number: | Click or tap here to enter text. |
| Study Title: | Click or tap here to enter text. |
| Short Title: | Click or tap here to enter text. |
| Site Investigator: | Click or tap here to enter text. |
| Site Primary Contact: | Click or tap here to enter text. |

Date WORKSHEET completed: Click or tap here to enter text.

**2. Organizational Responsibilities**

|  |  |
| --- | --- |
| **Reviewing IRB Requirements of Participating Sites (pSite)** | |
| Quality assurance/quality improvement program | ☐ QA/QI program access required  ☐ QA/QI program access not required  ☐ Other: Click or tap here to enter text. |
| Insurance | ☐ Insurance coverage (sufficient to cover its activities) required  ☐ Insurance not required  ☐ Other: Click or tap here to enter text. |
| Indemnification | ☐ Indemnification agreement required by one or more institutions  ☐ Indemnification agreement not required  ☐ Other: Click or tap here to enter text. |

|  |  |
| --- | --- |
| **Activity** | **Responsible Party** |
| Conducting Scientific Review. | ☐ Reviewing IRB  ☐ pSite  ☐ Other: Click or tap here to enter text. |
| Ensuring concordance between any applicable grant and the IRB application (Research under Pre-2018 Requirements only). | ☐ Reviewing IRB  ☐ pSite  ☐ Other: Click or tap here to enter text. |
| Reviewing potential non-compliance, including complaints, protocol deviations, and results of audits. | ☐ Reviewing IRB  ☐ pSite  ☐ Other: Click or tap here to enter text. |
| Organization responsible for deciding whether allegations of non-compliance have basis in fact. | ☐ Reviewing IRB  ☐ pSite  ☐ Other: Click or tap here to enter text. |
| Organization responsible for deciding whether each incident of non-compliance is serious or continuing. | ☐ Reviewing IRB  ☐ pSite  ☐ Other: Click or tap here to enter text. |
| Creating management plans for researcher and research staff conflicts of interest. **NOTE**: If the pSite maintains responsibility for this issue, the management plan must be provided. | ☐ Reviewing IRB  ☐ pSite  ☐ Other: Click or tap here to enter text. |
| Managing organizational conflicts of interest. | ☐ Reviewing IRB  ☐ pSite  ☐ Other: Click or tap here to enter text. |
| Ensuring continued oversight of active studies until closure or a mutually agreed upon transfer of the studies should early termination of the reliance agreement occur. | ☐ Reviewing IRB  ☐ pSite  ☐ Other: Click or tap here to enter text. |
| Privacy Board for issuing waivers of HIPAA authorization. | ☐ Reviewing IRB  ☐ pSite  ☐ Other: Click or tap here to enter text. |
| IRB-initiated external reporting (e.g., reporting to regulatory and funding agencies any reports of unanticipated problems, serious or continuing noncompliance, and suspension or termination of IRB approval). | ☐ Reviewing IRB  ☐ pSite  ☐ Other: Click or tap here to enter text. |
| NIH Genomic Data Sharing (GDS) Studies: Submission of Institutional Certification (Consult with Genomic Program Administrator from the funding NIH Institute or Center to discuss the appropriate certification) | ☐ Reviewing IRB  ☐ pSite  ☐ Other: Click or tap here to enter text. |
| Training & Qualifications: Providing the Reviewing IRB with confirmation that study teams at participating sites have completed relevant trainings and are qualified to conduct the proposed research. | ☐ Reviewing IRB  ☐ pSite  ☐ Other: Click or tap here to enter text. |
| Obtaining any additional approvals from DHHS when the research involves pregnant women, fetuses, and neonates; or children; or prisoners. | ☐ Reviewing IRB  ☐ pSite  ☐ Other: Click or tap here to enter text. |

**Notes:** Click or tap here to enter text.

1. This document satisfies AAHRPP element I-9 [↑](#footnote-ref-1)