HRP-830 | 3/29/2024

WORKSHEET: Communication & Responsibilities

The purpose of this worksheet is to provide support for the IRB 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]](#endnote-2)

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.

1. 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  Relying IRB  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.\*  \*For studies where the reviewing IRB will not serve as the Privacy Board, confirm there is no request for a HIPAA waiver or alteration.[[2]](#endnote-3) | 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 [↑](#endnote-ref-2)
2. Studies proposing to request a waiver or alteration of HIPAA authorization, must utilize an IRB that will also act as a privacy board for any reliance studies. [↑](#endnote-ref-3)