



HRP-830 | 2/2/2024

WORKSHEET: Communication & Responsibilities

The purpose of this worksheet is to provide support for the Reliance Coordinator or 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

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.

¹ This document satisfies AAHRPP element I-9

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.	☐ 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	☐ Reviewing IRB

unanticipated problems, serious or continuing noncompliance, and suspension or termination of IRB approval).	☐ 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 <u>participating sites</u> 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.