The purpose of this worksheet is to provide support for the Reliance Coordinator, HRPP staff or an Investigator when developing a communication plan and identifying roles and responsibilities of the IRB of Record, Relying sites and/or the Overall PI or Lead Study Team.

1 Organizational Responsibilities

Activity	Responsible Party
Education and Training: Providing education to researchers and research staff.	❑ Reviewing IRB ❑ Relying IRB ❑ Other:
Conducting Scientific Review	❑ Reviewing IRB ❑ Relying IRB ❑ Other:
Ensuring concordance between any applicable grant and the IRB application.	❑ Reviewing IRB ❑ Relying IRB ❑ Other:
Reviewing potential non-compliance, including complaints, protocol deviations, and results of audits	❑ Reviewing IRB ❑ Relying IRB ❑ Other:
Organization responsible for deciding whether allegations of non-compliance has basis in fact.	❑ Reviewing IRB ❑ Relying IRB ❑ Other:
Organization responsible for deciding whether each incident of non-compliance is serious or continuing.	❑ Reviewing IRB ❑ Relying IRB ❑ Other:
Obtaining management plans for researcher and research staff conflicts of interest. **NOTE:** If the relying organization maintains responsibility for this issue, the management plan must be provided	❑ Reviewing IRB ❑ Relying IRB ❑ Other:
Managing organizational conflicts of interest.	❑ Reviewing IRB ❑ Relying IRB ❑ Other:
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 ❑ Relying IRB ❑ Other:
Notes:	

2 Study-Specific Responsibilities

Training & Qualifications: Providing the IRB of record with confirmation that study teams at relying sites have completed relevant trainings and are qualified to conduct the proposed research.	❑ Reviewing IRB ❑ Relying IRB Contact ❑ Lead Study Team ❑ Relying Study team ❑ Other:
Local Context Information: Providing local context information (e.g., consent language, local laws, institutional requirements) to the reviewing IRB.	❑ Reviewing IRB ❑ Relying IRB Contact ❑ Lead Study Team ❑ Relying Study team ❑ Other:
IRB Application Materials: Preparing and submitting the study materials for initial or continuing review or submitting modifications to the sIRB.	❑ Reviewing IRB ❑ Relying IRB Contact ❑ Lead Study Team ❑ Relying Study team ❑ Other:
Site-specific Materials: Preparing and submitting site-specific materials to the sIRB.	❑ Reviewing IRB ❑ Relying IRB Contact ❑ Lead Study Team ❑ Relying Study team

	❑ Other:
IRB Determinations and IRB-Approved Documents: Providing sIRB determinations and approved study materials to participating sites.	❑ Reviewing IRB ❑ Relying IRB Contact ❑ Lead Study Team ❑ Relying Study team ❑ Other:
Templates: Providing study document templates (e.g., consent forms, recruitment materials) to participating sites.	❑ Reviewing IRB ❑ Relying IRB Contact ❑ Lead Study Team ❑ Relying Study team ❑ Other:
Policies of the sIRB: Providing the lead study team with all relevant sIRB policies	❑ Reviewing IRB ❑ Relying IRB Contact ❑ Lead Study Team ❑ Relying Study team ❑ Other:
pSite Continuing Review Information: Obtaining and collating CR information from all participating sites.	❑ Reviewing IRB ❑ Relying IRB Contact ❑ Lead Study Team ❑ Relying Study team ❑ Other:
Reportable New Information: Reporting RNI information to the sIRB for participating sites.	❑ Reviewing IRB ❑ Relying IRB Contact ❑ Lead Study Team ❑ Relying Study team ❑ Other:
Closing a Study: Reporting study closures to the sIRB	❑ Reviewing IRB ❑ Relying IRB Contact ❑ Lead Study Team ❑ Relying Study team ❑ Other:
Notes:	