|  |
| --- |
| 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:       |
|  |
|  |
| 1. 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:       |
|  |