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| 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]](#footnote-1) | |
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| 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. (Research under Pre-2018 Requirements only). | 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: |
| Privacy Board for issuing waivers of HIPAA authorization | Reviewing IRB  Relying IRB  Other: |
| Notes: | |
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| 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: |
| Ensuring organizational compliance with the requirements of other parts of the local HRPP and communicating to the external IRB. This includes obtaining approval from other internal review committees prior to IRB or EC approval. | 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. [[2]](#footnote-2) | 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.2 | 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: |
| Obtaining any additional approvals from DHHS when the research involves pregnant women, fetuses, and neonates; or children; or prisoners | Reviewing IRB  Relying IRB Contact  Lead Study Team  Relying Study team  Other: |
| 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  Relying IRB Contact  Lead Study Team  Relying Study team  Other: |
| Notes: | |
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1. This document satisfies AAHRPP element I-9 [↑](#footnote-ref-1)
2. See SMART IRB’s Guidance on Continuing Review Content Recommendations for Single IRB for recommendation on how to manage continuing review processes: <https://smartirb.org/assets/files/CR-ContentRec-HSC-TableExtract.pdf> [↑](#footnote-ref-2)