HRP-830 | 11/2/2023

WORKSHEET: Communication & Responsibilities

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]](#endnote-2)

1. Organizational Responsibilities

|  |  |
| --- | --- |
| **Activity** | **Responsible Party** |
| Determining whether the relying organization applies its FWA to some or all research, and ensuring the IRB of record review is consistent with requirements in the relying organization’s FWA. | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  Other: Click or tap here to enter text. |
| Education and Training: Providing education to researchers and research staff. | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  Other: Click or tap here to enter text. |
| Conducting Scientific Review. | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  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[ ]  Relying IRB[ ]  Other: Click or tap here to enter text. |
| Reviewing potential non-compliance, including complaints, protocol deviations, and results of audits. | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  Other: Click or tap here to enter text. |
| Organization responsible for deciding whether allegations of non-compliance have basis in fact. | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  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. |
| 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: Click or tap here to enter text. |
| Managing organizational conflicts of interest. | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  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[ ]  Relying IRB[ ]  Other: Click or tap here to enter text. |
| Privacy Board for issuing waivers of HIPAA authorization. | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  Other: Click or tap here to enter text. |

**Notes:** Click or tap here to enter text.

1. Study-Specific Responsibilities

|  |  |
| --- | --- |
| **Activity** | **Responsible Party** |
| 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[ ]  Lead Study Team[ ]  Relying Study Team[ ]  Other: Click or tap here to enter text. |
| Local Context Information: Providing local context information (e.g., consent language, local laws, institutional requirements) to the reviewing IRB. | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  Lead Study Team[ ]  Relying Study Team[ ]  Other: Click or tap here to enter text. |
| 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[ ]  Lead Study Team[ ]  Relying Study Team[ ]  Other: Click or tap here to enter text. |
| IRB Application Materials: Preparing and submitting the study materials for initial or continuing review or submitting modifications to the sIRB.[[2]](#endnote-3) | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  Lead Study Team[ ]  Relying Study Team[ ]  Other: Click or tap here to enter text. |
| Site-specific Materials: Preparing and submitting site-specific materials to the sIRB. | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  Lead Study Team[ ]  Relying Study Team[ ]  Other: Click or tap here to enter text. |
| IRB Determinations and IRB-Approved Documents: Providing sIRB determinations and approved study materials to participating sites. | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  Lead Study Team[ ]  Relying Study Team[ ]  Other: Click or tap here to enter text. |
| Templates: Providing study document templates (e.g., consent forms, recruitment materials) to participating sites.  | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  Lead Study Team[ ]  Relying Study Team[ ]  Other: Click or tap here to enter text. |
| Policies of the sIRB: Providing the lead study team with all relevant sIRB policies. | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  Lead Study Team[ ]  Relying Study Team[ ]  Other: Click or tap here to enter text. |
| pSite Continuing Review Information: Obtaining and collating CR information from all participating sites.[[3]](#endnote-4) | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  Lead Study Team[ ]  Relying Study Team[ ]  Other: Click or tap here to enter text. |
| Reportable New Information: Reporting RNI information to the sIRB for participating sites. | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  Lead Study Team[ ]  Relying Study Team[ ]  Other: Click or tap here to enter text. |
| Closing a Study: Reporting study closures to the sIRB. | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  Lead Study Team[ ]  Relying Study Team[ ]  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[ ]  Relying IRB[ ]  Lead Study Team[ ]  Relying Study Team[ ]  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[ ]  Relying IRB[ ]  Lead Study Team[ ]  Relying Study Team[ ]  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. 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> [↑](#endnote-ref-3)
3. Ibid. [↑](#endnote-ref-4)