|  |  |
| --- | --- |
| IRB Study #: |  |
| Study Title |  |

***Roles & Contacts***

| **Role** | **Institution** | **Contact Information/Notes** |
| --- | --- | --- |
| Lead study team |  |  |
| Site-Specific PIs | Relying Sites  |  |
| Reviewing IRB Point of Contact (POC) |  |  |
| Single IRB Coordinator(sIRB Coordinator) |  | *Individual responsible for IRB submissions for all sites; Indiana University CTSI may be able to provide resources toward this effort.*  |
| Relying Site IRB/HRPP POC | Relying Sites |  |

***Communication Plan***

*Use the following table to describe who will be responsible for each communication piece associated with IRB-related issues, and the process for doing so. The Responsible Party and Process Notes columns include examples of processes which may be acceptable; however, they should be customized for each study.*

| **Communication Responsibility** | **Responsible Party** | **Process Notes** |
| --- | --- | --- |
| **Site-Start Up**  |
| **Communicate IRB Process to Relying Sites**: Letter providing overview of IU IRB and reliance process to Relying Site POCs and Site-Specific PIs; attach relevant information  | sIRB Coordinator | Reviewing IRB POC will help draft letter and documents; sIRB Coordinator will distribute to all Site-Specific PIs and Relying Site IRB/HRPP POCAttachments:* Communication plan
* SMART IRB Agreement Implementation Checklist
* Relying Site Local Context Sheet
* Relying Site Personnel List
* Protocol
* ICS template & instructions (what can be customized)
* HIPAA template
 |
| **Platform for reliance: \_\_\_** | Lead study team  | All participating sites must be willing to use the identified reliance platform and any appropriate signatures need to be completed  |
| **[Reliance platform]**: Create study; initiate request for reliance | Reviewing IRB POC |  |
| **[Reliance platform]**: Indicate reliance acceptance  | Relying Site IRB/HRPP POC |  |
| **Reviewing IRB Policies:** Providing relevant Reviewing IRB policies to Site-Specific PIs and ensuring appropriate training  | sIRB CoordinatorLead study team |  |
| **Relying Site IRB Submissions**: Preparing and submitting Relying Site local IRB applications  | sIRB Coordinator | Dependent on Relying Site IRB requirements  |
| **Local Context Information**  |
| **Study Team Training & Qualification**: Providing confirmation to the Reviewing IRB that relying site study teams are qualified and eligible to conduct the proposed research and have completed relevant training *(via Relying Site Local Context Checklist)* | Relying Site IRB/HRPP POC | 1. Relying Site IRB/HRPP POC will complete Relying Site Local Context Checklist
2. sIRB Coordinator will ensure completion prior to submission of amendment to add Relying Site
3. Reviewing IRB POC will provide completed Relying Site Local Context Checklist with amendment documents
 |
| **COI**: Providing applicable conflict of interest disclosure information and management plans for relying site study teams to the Reviewing IRB *(via Relying Site Local Context Checklist)*  | Relying Site IRB/HRPP POC  |
| **Local Context Information**: Providing local context information to the Reviewing IRB regarding state laws and institutional requirements that pertain to the review of the protocol | Relying Site IRB/HRPP POC |
| **Personnel List**: Providing list of relying site research personnel, their roles, and any potential COI information to Reviewing IRB *(via Relying Site Personnel List)* | Site-Specific PIRelying Site IRB/HRPP POC | 1. Site-Specific PI will complete and sign Relying Site Personnel List
2. Relying Site IRB/HRPP POC will review and sign
3. Completed form should be provided to sIRB Coordinator
4. sIRB Coordinator will provide to Reviewing IRB with amendment to add Relying Site
 |
| **Consent Form Language**: Incorporating site-specific language into consent form(s) and providing these consent form(s) to the Reviewing IRB with amendment to add Relying Site | sIRB Coordinator |  |
| **IRB Submissions & Documentation** |  |  |
| **IRB Application – Protocol + IU Site**: Preparing and submitting the application for initial IRB review (including: final protocol, final ICS template, IU site-specific ICS, communication plan) via KC IRB | sIRB Coordinator | Submitted via KC IRB  |
| **IRB Application – Site Specific**: Preparing and submitting the site-specific amendments to the Reviewing IRB that address site variations in study conduct, informed consent language, HIPAA Privacy Rule requirements, subject identification and recruitment processes (including recruitment materials), and any other applicable components of the research | sIRB Coordinator | Must include:* Relying Site Local Context Checklist
* Relying Site Personnel List

Submitted via KC IRB |
| **IRB Determinations**: Providing documentation of IRB determinations to the lead study team and Site-Specific PIs, [in a timely manner (describe)] | sIRB PM | Disseminated via [Reliance platform] |
| **IRB-Approved Documents**: Providing copies of IRB-approved materials to the lead study team and Site-Specific PIs, including site-specific documents and materials, [in a timely manner (describe)] | sIRB PM | Disseminated via [Reliance platform]Documents include:* Signed Protocol Summary
* Approval Letter
* Approved documents
* Site-specific documents (stamped ICS, recruitment materials)
 |
| **Amendment Requests**: Requesting site-specific amendments (e.g. personnel changes, recruitment materials, etc)  | Site-Specific PI  |  |
| **Amendment Review:** Reviewing amendment requests for appropriateness | Lead study team |  |
| **Amendment Submissions**: Submitting amendments, including personnel changes, to the Reviewing IRB via KC IRB | sIRB Coordinator | Submitted via KC IRB |
| **Site-Specific Renewal Information**: Providing site-specific information (enrollment, problems, etc) for inclusion in renewal submissions | Site-Specific PI |  |
| **Renewal Information**: Obtaining and collating studywide information for renewal to the Reviewing IRB | sIRB PM |  |
| **Renewal Submission**: Submitting renewal to the Reviewing IRB via KC IRB | sIRB PM | Submitted via KC IRB |
| **Reportable Event Notification**: Reporting site-specific reportable events to the sIRB Coordinator | Site-Specific PI  |  |
| **Reportable Event Review:** Reviewing reportable events to determine whether they meet Reviewing IRB prompt reporting criteria | Lead study team |  |
| **Reportable Event Submissions**: Submitting reportable events to the Reviewing IRB (e.g., unanticipated problems, noncompliance, subject complaints) via KC IRB | sIRB Coordinator | Submitted via KC IRB |
| **Closure Reports:** Providing Reviewing IRB and Relying Site IRB/HRPP POCs with required information when a study is closed. | sIRB Coordinator | Submitted via KC IRB |