|  |
| --- |
| Purpose of the form: This form can be used by Reviewing IRBs and others to identify and document key communication roles for a study. It is recommended that the form be used to document the various responsibilities. However, the form also could be used less formally to guide conversations between the Reviewing IRB, Relying Institutions, and Lead Study Team. |

**Communication Plan**

*Definitions*

* Point of Contact (POC) – REVIEWING IRB: Main person responsible for addressing questions related to the Reviewing IRB’s policies and procedures and review status for a ceded study
* Point of Contact (POC) – LEAD STUDY TEAM: Main person responsible for communication with the Reviewing IRB and facilitating communication between relying site study teams and the Reviewing IRB regarding the ceded study
* Point of Contact (POC) – RELYING SITE: Main person responsible for communication with the Reviewing IRB and local study team regarding the ceded study (e.g., personnel in the local IRB office or local human research protection program personnel)
* Point of Contact (POC) – RELYING SITE STUDY TEAM: Main person responsible for communication with the Lead Study Team regarding the ceded study

|  |  |  |
| --- | --- | --- |
| **Role** | **Name(s)** | **Contact Information** |
| POC – REVIEWING IRB | *UT Health San Antonio IRB* | *210-567-8250; IRB@uthscsa.edu* |
| POC – LEAD STUDY TEAM | *XXX* | *XXX* |
| POC – Relying Site Study Team | *XXX* | *XXX* |
|  POC- Relying Site IRB/Equivalent office | *XXX* | *XXX* |

***Communication Plan***

| **Communication Responsibility** | **Source of Information**  | **Note** |
| --- | --- | --- |
| COI: Providing applicable conflict of interest management plans for relying site study teams to the Reviewing IRB[ ] N/A – Documentation for this requirement has been included on the **Single IRB** **Protocol Specific Form**[ ]  N/A Documentation for this requirement has been included on the **Form K-2** | [ ]  Reviewing IRB[ ]  Lead Study Team[ ]  Relying Site Study Team[x]  Relying Site IRB/Equivalent office[ ]  Other, specify:  | * Relying Site Study Teams POC sends COI management plan(s) to Lead Study Team
* Lead Study Team POC forwards COI management plans to Reviewing IRB.
 |
| STUDY TEAM TRAINING & QUALIFICATIONS: [ ] N/A – Documentation for this requirement has been included on the **Single IRB** **Protocol Specific Form**[ ]  N/A Documentation for this requirement has been included on the **Agreement Implementation Checklist and Documentation Tool**[ ]  N/A Documentation for this requirement has been included on the **Form K-2** | [ ]  Reviewing IRB[ ]  Lead Study Team[ ]  Relying Site Study Team[x]  Relying Site IRB/Equivalent office[ ]  Other, specify:  | Training for Research personnel from ceding institution will be verified and confirmed upon initial review and throughout the life of the study by the ceding institution. Only the individuals who conducts research at UT Health San Antonio or an affiliated study site; the research or a research procedure requires specialized skills and/or training by the IRB; the individual has a conflict of interest; the individual will be listed in the informed consent document; site principal investigators; and/or will be listed as the overall principal investigator. In these situations, UT Health San Antonio requires that the individual be named in the research application.* (
 |
| LOCAL CONTEXT INFORMATION: Providing local context information to the Reviewing IRB regarding state laws and institutional requirements that pertain to the review of the ceded study[ ] N/A – Documentation for this requirement has been included on the **Single IRB** **Protocol Specific Form**[ ]  N/A Documentation for this requirement has been included on the **Form K-2** | [ ]  Reviewing IRB[ ]  Lead Study Team[ ]  Relying Site Study Team[x]  Relying Site IRB/Equivalent office[ ]  Other, specify:  | * Relying Site Study Team(s) must work with the Relying Site IRB/Equivalent office POC to identify local context information. The Relying Site Study Team/Relying Site IRB/Equivalent office POC communicates requirements of the Relying Site’s local context information to the Lead Study Team POC.
* Lead Study Team communicates/submits requirements to the Reviewing IRB.
 |
| IRB APPLICATION – STUDYWIDE: Preparing and submitting the study-wide application for initial IRB review and study-wide amendments to the Reviewing IRB | [ ]  Reviewing IRB[x]  Lead Study Team[ ]  Relying Site Study Team[ ]  Relying Site POC[ ]  Other, specify:  | * Lead Study Team prepares, reviews and submits study-wide applications for initial IRB review and amendments to protocols to Reviewing IRB.
* Approval letters are sent to the Lead Study Team and the Relying Site IRB/Equivalent office POCs by Reviewing IRB. Lead Study Team POC is responsible for disseminating IRB approved protocols and study related documents (initial and any amended) to Relying Site Study Teams. Relying site PIs are responsible for providing copies and communicating protocol specifics to Relying Site Study Team members.
 |
| IRB APPLICATION – SITE SPECIFIC: Preparing and submitting the site-specific applications and 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[ ] N/A – Documentation for this requirement has been included on the **Single IRB** **Protocol Specific Form**[ ]  N/A Documentation for this requirement has been included on the **Agreement Implementation Checklist and Documentation Tool**[ ]  N/A Documentation for this requirement has been included on the **Form K-2** | [ ]  Reviewing IRB[ ]  Lead Study Team[x]  Relying Site Study Team[ ]  Relying Site IRB/Equivalent office POC[ ]  Other, specify:  | * Relying Site Study Teams prepare and submit site-specific applications and amendments to Relying Site IRB/Equivalent office POCs as needed. If not needed, documents are sent directly to Lead Study Team POC who will then forward and prepare any IRB required documentation to Reviewing IRB.
* Relying Site IRB/Equivalent office POC may communicate directly with Reviewing IRB as needed.
* Reviewing IRB notifies Relying Site IRB/Equivalent office POC and Lead Study Team POC of IRB approval and sends IRB approved documents. Lead Study Team POC communicates directly to Relying Site Study Team. Relying Site Study Teams are responsible for communicating changes to protocol directly to Relying Site Study Team members.
 |
| IRB DETERMINATIONS: Providing documentation of IRB determinations to relying site study teams | [ ]  Reviewing IRB[x]  Lead Study Team[ ]  Relying Site Study Team[ ]  Relying Site IRB/Equivalent office POC[ ]  Other, specify:  | * Reviewing IRB communicates determinations to Lead Study Team POC and to the Relying Site IRB/Equivalent office POC.
* Lead Study Team POC communicates determinations to relying Site Study Teams. Relying Site Study Teams are responsible for communicating changes to protocol directly to Relying Site Study Team members.
 |
| IRB-APPROVED DOCUMENTS: Providing copies of IRB-approved materials to the lead study team | [ ]  Reviewing IRB[x]  Lead Study Team[ ]  Relying Site Study Team[ ]  Relying Site IRB/Equivalent office POC[ ]  Other, specify: | * Reviewing IRB provides copies of IRB-approved materials to Lead Study Team POC. Lead Study Team POC provides copies to Lead Study Team members at which time all parties review and confirm accuracy of approved documents.
 |
| IRB-APPROVED DOCUMENTS – RELYING SITES: Providing copies of the most current versions of IRB-approved materials to relying site study teams in a timely manner  | [ ]  Reviewing IRB[x]  Lead Study Team[ ]  Relying Site Study Team[ ]  Relying Site IRB/Equivalent office POC[ ]  Other, specify: | * Upon approval of initial studies and amendments, the Reviewing IRB will provide copies of IRB approved documents the Lead Study Team POC and copy the Relying Site(s) POC(s). Lead Study Team POC will provide copies to Relying Site Study Team(s). Relying Site Study Team(s)are responsible for disseminating information to their respective Relying Site Study Team Members.
 |
| CONSENT FORM TEMPLATE: Providing the consent form template to relying site study teams | [x]  Reviewing IRB[ ]  Lead Study Team[ ]  Relying Site Study Team[ ]  Relying Site IRB/Equivalent office POC[ ]  Other, specify: | * Reviewing IRB posts consent templates on the website.
* Lead Study Team POC disseminates this information to the Relying Study team.
 |
| CONSENT FORM LANGUAGE: Incorporating site-specific language into consent form(s) and providing these consent form(s) to the Reviewing IRB[ ] N/A – Documentation for this requirement has been included on the **Single IRB** **Protocol Specific Form**[ ]  N/A Documentation for this requirement has been included on the **Form K-2** | [ ]  Reviewing IRB[ ]  Lead Study Team[ ]  Relying Site Study Team[x]  Relying Site IRB/Equivalent office POC[ ]  Other, specify: | * Relying Site IRB/Equivalent office POC notifies the Lead Study Team POC of the required language and the Lead Study Team POC submits these forms to the Reviewing IRB
 |
| REVIEWING IRB POLICIES: Providing relevant Reviewing IRB policies to the lead study team | [x]  Reviewing IRB[ ]  Lead Study Team[ ]  Relying Site Study Team[ ]  Relying Site IRB/Equivalent office POC[ ]  Other, specify: | * Reviewing IRB responsible for maintaining current policies on website.
* Lead Study Team responsible for accessing IRB policies directly from IRB Website: http://research.uthscsa.edu/irb/
 |
| PROTOCOL AMENDMENTS: | [ ]  Reviewing IRB[x]  Lead Study Team[ ]  Relying Site Study Team[ ]  Relying Site IRB/Equivalent office POC[ ]  Other, specify: | * Lead Study Team is responsible for submitting amendments (studywide or local amendments for Relying Sites) to the Reviewing IRB for review in accordance with the Reviewing IRB’s policies and procedures (e.g., timing and mechanism of submission).
* The Reviewing IRB will notify the Lead Study Team and Relying Site when it has approved an amendment/change in research through its established processes.
 |
| CONTINUING REVIEW INFORMATION: Obtaining and collating study-wide information for continuing review to the Reviewing IRB | [ ]  Reviewing IRB[x]  Lead Study Team[ ]  Relying Site Study Team[ ]  Relying Site IRB/Equivalent office POC[ ]  Other, specify: | * Lead Study Team POC requests continuing review information from Relying Site Study Team(s).
* Relying Site Study Team(s) provide requested information to Lead Study Team POC. Lead Study Team POC completes continuing review report and submits to Reviewing IRB for approval.
 |
| CONTINUING REVIEW SUBMISSION: Submitting continuing review progress report to the Reviewing IRB | [ ]  Reviewing IRB[x]  Lead Study Team[ ]  Relying Site Study Team[ ]  Relying Site IRB/Equivalent office POC[ ]  Other, specify: | * Lead Study Team POC requests continuing review information from Relying Site Study Team(s).
* Relying Site Study Team(s) provide requested information to Lead Study Team POC. Lead Study Team POC completes continuing review report and submits to Reviewing IRB for approval.
 |
| REPORTABLE EVENTS: Reporting reportable events to the Reviewing IRB (e.g., unanticipated problems, noncompliance, subject complaints) | [ ]  Reviewing IRB[x]  Lead Study Team[ ]  Relying Site Study Team[ ]  Relying Site IRB/Equivalent office POC[ ]  Other, specify: | * The Relying Site Study Team(s) reports events to the Lead Study Team POC. The Lead Study Team POC evaluates whether the event meets criteria for prompt reporting. If it does, the Lead Study Team POC will promptly report event to the Reviewing IRB. If it does not require prompt reporting, the event will be logged and summarized during continuing review.
* When a reportable event occurs at the Lead Site, the Lead Study Team POC evaluates whether the event meets criteria for prompt reporting. If it does, the Lead Study Team POC will promptly report event to the Reviewing IRB. If it does not require prompt reporting, the event will be logged and summarized during continuing review.

Reviewing IRB will send final determinations to the Lead Study Team POC and Relying Site(s) POC(s). It is the responsibility of Lead Study Team POC to disseminate the IRB determination to the Lead and Relying Site Study Team(s). |
| REPORTABLE EVENTS: For Privacy related issues (include the plan for ensuring the Reviewing IRB is informed of how the event was evaluated (e.g., HIPAA Incident or HIPAA Violation) and whether there are additional actions required by the institution’s Privacy Officer) | [x]  Lead Study Team[ ]  Relying Site Study Team[ ]  Relying Site IRB/Equivalent office POC[ ]  Other, specify: | * The Relying Site Study Team(s) reports events to the Lead Study Team POC. The Relying Site Study Team(s) reports the event to their respective Privacy Office. Notice on the Privacy Office determination to include how the event was evaluated (e.g., HIPAA Incident or HIPAA Violation) and whether there are additional actions required by the institution’s Privacy Office.
 |
| CLOSURE REPORTS: Providing the Reviewing IRB with required information when a study is closed. | [ ]  Reviewing IRB[x]  Lead Study Team[ ]  Relying Site Study Team[ ]  Relying Site IRB/Equivalent office POC[ ]  Other, specify: | * When a Relying Site is closed, Relying Site Study Team(s) must communicate to the Lead Study Team POC, who will then complete documentation to submit to the Reviewing IRB. This will be an amendment. Once approved, the approved documentation is disseminated from the Reviewing IRB to the Lead Study Team POC and Relying Site(s) POC(s). It is the responsibility of Lead Study Team POC to disseminate the IRB determination to the Relying Site Study Team(s).
* If the entire study is closed, Lead Study Team POC requests any needed information from Relying Site Study Team(s) and completes an inactivation request and submits to Reviewing IRB.
 |
| UPDATING GENERAL INFORMATION: Providing the Reviewing IRB with required information as it relates to conducting the study at the Relying Study Site. | [ ]  Reviewing IRB[ ]  Lead Study Team[ ]  Relying Site Study Team[ ]  Relying Site IRB/Equivalent office POC[ ]  Other, specify: | * Relying Site Study Team or equivalent will notify Reviewing IRB of changes that may affect the conduct of the study. (e.g., laws, local context language, vulnerable populations.
 |

Additional Communication Plan: REQUIRED - Include plan for routine communication between Study PI/Team and Relying PI/Team (e.g. conf calls)