# Communication Plan

| COMMUNICATION RESPONSIBILITY | RESPONSIBLE PARTY | NOTES |
|---|---|---|
| **COI:** Providing applicable conflict of interest management plans for relying site study teams to the Reviewing IRB | ☐ Reviewing IRB - POC<br>☐ Lead Study Team - POC<br>☑ Relying Site Study Team -<br>☐ POC Relying Site IRB/HRPP -<br>☐ POC Other, specify: | The Relying Institution(s) will perform their own analyses under their relevant policy(ies) with respect to disclosure and management of their Research Personnel's conflicts of interest in connection with the identified study(ies). The Relying Institution's(s') resulting determinations, prohibitions, management plans, and any updates will be provided to the Reviewing IRB. Note that the Reviewing IRB has the right to impose additional prohibitions or conflict management requirements. |
| **STUDY TEAM TRAINING & QUALIFICATIONS:** Providing confirmation to the Reviewing IRB that relying site study teams have completed relevant training and are qualified to conduct the proposed research | ☐ Reviewing IRB - POC<br>☐ Lead Study Team - POC<br>☐ Relying Site Study Team - POC<br>☑ Relying Site IRB/HRPP - POC<br>☐ Other, specify: | Relying Institution investigators will comply with the Relying Institution's investigator ethics education requirement and other human research related policies. |
| **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 | ☐ Reviewing IRB - POC<br>☐ Lead Study Team - POC<br>☐ Relying Site Study Team - POC<br>☑ Relying Site IRB/HRPP - POC<br>☐ Other, specify: | Relying institutions are responsible for communicating to UTSW IRB the requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local ancillary reviews, relevant to the research that would affect the conduct of the research at the Relying Institution. |
| **IRB APPLICATION – STUDYWIDE:** Preparing and submitting the studywide application for initial IRB review and studywide amendments to the Reviewing IRB | ☐ Reviewing IRB - POC<br>☑ Lead Study Team - POC<br>☐ Relying Site Study Team - POC<br>☐ Relying Site IRB/HRPP - POC<br>☐ Other, specify: | HRPP Policy 2.1 Initial Review of Research<br><br>HRPP Policy 2.3 Modifications to Research |


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| **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 | ☐ Reviewing IRB - POC<br>☑ Lead Study Team - POC<br>☐ Relying Site Study Team - POC<br>☐ Relying Site IRB/HRPP - POC<br>☐ Other, specify: | |
| **IRB DETERMINATIONS:** Providing documentation of IRB determinations to relying site study teams | ☐ Reviewing IRB - POC<br>☑ Lead Study Team - POC<br>☐ Relying Site Study Team - POC<br>☐ Relying Site IRB/HRPP - POC<br>☐ Other, specify: | |
| **IRB-APPROVED DOCUMENTS:** Providing copies of IRB-approved materials to the lead study team | ☑ Reviewing IRB - POC<br>☐ Lead Study Team - POC<br>☐ Relying Site Study Team - POC<br>☐ Relying Site IRB/HRPP - POC<br>☐ Other, specify: | |
| **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 - POC<br>☑ Lead Study Team - POC<br>☐ Relying Site Study Team - POC<br>☐ Relying Site IRB/HRPP - POC<br>☐ Other, specify: | |


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| **CONSENT FORM TEMPLATE:** Providing the consent form template to relying site study teams | ☐ Reviewing IRB - POC<br>☑ Lead Study Team - POC<br>☐ Relying Site Study Team - POC<br>☐ Relying Site IRB/HRPP - POC<br>☐ Other, specify: | |
| **CONSENT FORM LANGUAGE:** Incorporating site-specific language into consent form(s) and providing these consent form(s) to the Reviewing IRB | ☐ Reviewing IRB - POC<br>☑ Lead Study Team - POC<br>☑ Relying Site Study Team - POC<br>☐ Relying Site IRB/HRPP - POC<br>☐ Other, specify: | The relying site study team(s) will incorporate their site-specific language into consent form(s) and send to lead study team for submission to Reviewing IRB. |
| **REVIEWING IRB POLICIES:** Providing relevant Reviewing IRB policies to the relying site study team(s) | ☐ Reviewing IRB - POC<br>☑ Lead Study Team - POC<br>☐ Relying Site Study Team - POC<br>☐ Relying Site IRB/HRPP - POC<br>☐ Other, specify: | The University of Texas Southwestern Medical Center will follow UTSW's HRPP policies and procedures. |
| **CONTINUING REVIEW INFORMATION:** Obtaining and collating studywide information for continuing review to the Reviewing IRB | ☐ Reviewing IRB - POC<br>☑ Lead Study Team - POC<br>☐ Relying Site Study Team - POC<br>☐ Relying Site IRB/HRPP - POC<br>Other, specify: | Continuing Review/Annual Update Progress Report |


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| **CONTINUING REVIEW SUBMISSION:** Submitting continuing review progress report to the Reviewing IRB | ☐ Reviewing IRB - POC<br>☑ Lead Study Team - POC<br>☐ Relying Site Study Team - POC<br>☐ Relying Site IRB/HRPP - POC<br>☐ Other, specify: | |
| **REPORTABLE EVENTS:** Reporting reportable events to the Reviewing IRB (e.g., unanticipated problems, noncompliance, subject complaints) | ☐ Reviewing IRB - POC<br>☑ Lead Study Team - POC<br>☐ Relying Site Study Team - POC<br>☐ Relying Site IRB/HRPP - POC<br>☐ Other, specify: | HRPP Policy and Procedures 9. Compliance |
| **CLOSURE REPORTS:** Providing the Reviewing IRB with required information when a study is closed. | ☐ Reviewing IRB - POC<br>☑ Lead Study Team - POC<br>☐ Relying Site Study Team - POC<br>☐ Relying Site IRB/HRPP - POC<br>☐ Other, specify: | HRPP Policy and Procedures<br>1.4. STUDY CLOSURE AND INACTIVATION |


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