**Template Communication Plan for Reliance Agreements, including SMART IRB**

**(University of Michigan IRB-HSBS as the Reviewing IRB)**

**HUM:**

**Study Title:**

**U-M Principal Investigator:**

*Definitions*

* REVIEWING IRB Point of Contact (POC): IRB-HSBS contact person responsible for addressing questions related to the IRB-HSBS' (Reviewing IRB) policies and procedures and review status for a ceded study
* LEAD STUDY TEAM POC: U-M study team member responsible for communicating with the IRB-HSBS (Reviewing IRB) and facilitating communication between relying site study teams and the IRB-HSBS (Reviewing IRB) regarding the ceded study
* RELYING SITE IRB POC: IRB contact person at the Relying Institution responsible for communicating with the IRB-HSBS (Reviewing IRB) and also with the relying site study team regarding the ceded study
* RELYING SITE STUDY TEAM POC: Main relying site study team member responsible for communicating the U-M Lead Study Team POC regarding the ceded study

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| **Role** | **Name(s)** | **Contact Information** |
| REVIEWING IRB POC |  |  |
| LEAD STUDY TEAM POC |  |  |
| RELYING SITE IRB POC |  |  |
| RELYING SITE STUDY TEAM POC |  |  |

***Communication Plan***

| **Communication Responsibility** | **Responsible Party** | **Notes** |
| --- | --- | --- |
| COI: Providing applicable conflict of interest management plans for relying site study teams to the Reviewing IRB | [ ]  Relying Site(s) IRB POC(s) |  |
| 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 | [ ]  Relying Site(s) POC(s) |  |
| 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 | [ ]  Relying Site(s) IRB POC(s) |  |
| IRB APPLICATION – STUDYWIDE: Preparing and submitting the studywide application for initial IRB review and studywide amendments to the Reviewing IRB | [ ]  U-M (Lead) Study Team  |  |
| 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 | [ ]  U-M (Lead) Study Team -or-[ ]  Relying Site Study Team(s)  | If the study involves fewer than 3 sites, the U-M study team will submit the site-specific information (in consultation with the Relying Site study team) to the IRB-HSBS.If the study uses the Multi-Site and Participating Sites applications, the Relying Site Study Team will submit this information to the IRB-HSBS. |
| IRB DETERMINATIONS: Providing documentation of IRB determinations to relying site study teams | [ ]  IRB-HSBS (Reviewing IRB) -or-[ ]  U-M (Lead) Study Team | If the study involves fewer than 3 sites, the U-M study team will provide documentation of IRB determinations to the relying site study teams.If the study uses the Multi-Site and Participating Sites applications, the IRB-HSBS will provide documentation to relying site study team via eResearch. |
| IRB-APPROVED DOCUMENTS: Providing copies of IRB-approved materials to the U-M (lead) study team | [ ]  IRB-HSBS (Reviewing IRB) | Approved documents are found in under the DOCUMENTS tab in the eResearch study workspace. |
| 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  | [ ]  U-M (Lead) Study Team -or-[ ]  IRB-HSBS (Reviewing IRB)  | If the study involves fewer than 3 sites, the U-M study team will provide documentation of IRB determinations to the relying site study teams.If the study uses the Multi-Site and Participating Sites applications, the IRB-HSBS will provide documentation to relying site study team via eResearch. |
| CONSENT FORM TEMPLATE: Providing the consent form template to relying site study teams | [ ]  U-M (Lead) Study Team -or-[ ]  IRB-HSBS (Reviewing IRB)  | If the study involves fewer than 3 sites, the U-M study team will provide documentation of IRB determinations to the relying site study teams.If the study uses the Multi-Site and Participating Sites applications, the IRB-HSBS will provide documentation to relying site study team via eResearch |
| CONSENT FORM LANGUAGE: Incorporating site-specific language into consent form(s) and providing these consent form(s) to the Reviewing IRB | [ ]  U-M (Lead) Study Team -or- [ ]  Relying Site Study Team(s) | If the study involves fewer than 3 sites, the U-M study team will submit consent templates including the site-specific language (in consultation with the Relying Site study team).If the study uses the Multi-Site and Participating Sites applications, the Relying Site Study Team will submit this information to IRB-HSBS via eResearch. |
| REVIEWING IRB POLICIES: Providing relevant Reviewing IRB policies to the lead study team | [ ]  IRB-HSBS (Reviewing IRB) |  |
| CONTINUING REVIEW INFORMATION: Obtaining and collating studywide information for continuing review to the Reviewing IRB (Note - most research reviewed by IRB-HSBS is minimal risk and continuing review is not required.) | [ ]  U-M (Lead) Study Team -or-[ ]  Relying Site Study Team(s) | If the study involves fewer than 3 sites, the U-M study team will obtain the required information for continuing review from Relying Site Study Teams and provide via SCR to the IRB-HSBS (Reviewing IRB).If the study uses the Multi-Site and Participating Sites applications, the Relying Site Study Team will provide required continuing review information to the IRB-HSBS (Reviewing IRB) via the Participating Sites application in eResearch. |
| CONTINUING REVIEW SUBMISSION: Submitting continuing review progress report to the Reviewing IRB | [ ]  U-M (Lead) Study Team |  |
| REPORTABLE EVENTS: Reporting reportable events to the Reviewing IRB (e.g., unanticipated problems, noncompliance, subject complaints) | [ ]  U-M (Lead )Study Team[ ]  Relying Site Study Team(s)[ ]  Relying Site(s) POC(s) | If the study involves fewer than 3 sites, the relying site study team or the Relying Site IRB POC will submit reportable events to the U-M (Lead) Study team who will then submit to the IRB-HSBS (Reviewing IRB). If the study uses the Multi-Site and Participating Sites applications, the Relying Site Study Team will submit reportable events to the IRB-HSBS (Reviewing IRB) via the Participating Sites application in eResearch. |
| CLOSURE REPORTS: Providing the Reviewing IRB with required information when a study is closed. | [ ]  U-M (Lead) Study Team |  |