**Relying Site Local Context Form and Communication Plan**

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| **Study Title** |  |
| **UChicago Protocol #** |  |
| **UChicago PI name** |  |
| **Site Principal Investigator** |  |

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| **Section 1: Institutional Information** –Relying Site |
| **Name of Site** |  |
| **Name of Site Point of Contact (Relying Study Team)** |  |
| **Contact Phone Number** |  |
| **Contact E-mail** |  |
| **Federalwide Assurance (FWA)**  | FWA#: FWA Expiration:Does the FWA extend to non-federally funded research? YES[ ]  NO[ ]   |
| **Site Specific Organizational Questions** | Provide any other names the site is known by: Identify any affiliations this site has relevant to this study, such as a university, clinic, or hospital: If any of the sites identified in question 3 above are within a network or system, do they have a separate FWA?YES[ ]  NO[ ]  If Yes, what are the sites with separate FWA *(note that each of those sites will need to complete this form)*: |
| **Does your site have an IRB/HRPP Office (or similar)?** | YES[ ]  NO[ ]  URL for the IRB/HRPP (*if applicable*): |
| **Does your site have a quality assurance (QA)/audit group responsible for overseeing ongoing research?** | YES[ ]  NO[ ]  *If YES, provide the QA contact information:*URL for the QA/HRPP (*if applicable*): |
| **Are there any investigations, audits, or findings (e.g. OHRP, FDA, or local audits) over the past 3 years that would be relevant to the conduct of human subjects’ research at your site?** | YES[ ]  NO[ ]  *If YES, please provide explanation here:* |
| **Is your site a covered entity under HIPAA?** | YES[ ]  NO[ ]  Hybrid[ ]  *If Hybrid, does this work fall under the covered component?*YES[ ]  NO[ ]   |
| **What human subjects’ protection training course(s) are completed by researchers at your site?** (e.g. CITI, GCP, NIH Protecting Human Research Participants Course, OHRP Training Modules, etc.): |  |
| **Please verify all site personnel engaged in this research are appropriately qualified and up to date with site institutionally required training (e.g. human subjects protections or HIPAA training).** | YES[ ]  NO[ ]  |
| **Financial Conflicts of Interest**NOTE: For any interests determined to constitute an FCOI or require a management plan, applicable management plans must be supplied with this completed form.  |
| **Please indicate whether a Financial Conflict of Interest has been identified that is relevant for this research:**  | YES[ ]  NO[ ]  If Yes, explain: |
| **Site Specific Activities** Will your site interact with, consent or recruit any research participants as part of their involvement in this study?  | YES[ ]  NO[ ]  If no, please skip to Section 5: HRPP Communication Plan for Relying Sites  |

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| **Section 2: Regulatory Requirements** |
| **Describe any local, state, or federal laws or requirements that would impact this research protocol or informed consent document (wards of the state, emancipated minors, etc):** |  |
| **Please outline any specific changes to the research that are required based on local, state, or federal requirements identified above:** |  |
| **What is the Age of Majority at your site?**  |  |

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| **Section 3: Institutional Requirements & Ancillary Reviews**  |
| **Describe any institutional requirements that apply to this study which require changes to the conduct of the study at your site:**  |  |
| **Outline specific changes to the research based on the requirements identified above:** |  |
| **Are any ancillary reviews required at your site [e.g. HIPAA Privacy Board, institutional biosafety (IBC) review for research with biospecimens, etc.]?** | YES[ ]  NO[ ]  None required[ ] *If YES, list ancillary reviews:* |
| **Template consent form requires site-specific language changes (other than research –related injury)?** | Is site-specific template language required? YES[ ]  NO[ ]  Not Applicable[ ]  *If YES, please list:*  |
| **Site-Specific Research-Related Injury Language** | Please include or attach: |
| **HIPAA authorization language** | Will a site-specific, stand-alone HIPAA form be used?  YES[ ]  NO[ ]  Not Applicable[ ] Alternatively, does your site permit a combined ICF/HIPAA form?YES[ ]  NO[ ]  Is waiver of authorization requested?YES[ ]  NO[ ]  YES, FOR SCREENING PURPOSES ONLY [ ]   |
| **Short-form consent** | If applicable to the research, does your site allow a short-form consent process for non-English speaking participants? YES[ ]  NO[ ]  Not applicable[ ]  *If YES, please provide a URL to the short-form consents available at your site:* |

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| **Section 4: Community Considerations**  |
| Are there any special community characteristics/concerns or subject population concerns of which the UChicago BSD IRB should be aware for this study?  | YES[ ]  NO[ ]  Not applicable [ ] *If YES, please describe:* |

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| Section 5: HRPP Communication Plan for Relying Sites- Below is a summary of which party of responsible for which study activity. Please check the appropriate box regarding HIPAA. If your site has comments or revisions for the remaining study activities, please comment in the note section below.  |
| Activity | Responsible Party |
| **HIPAA:** Privacy Board for issuing waivers of HIPAA authorization | [ ]  Reviewing IRB[ ]  Relying IRB[ ]  Other: Click or tap here to enter text. |
| **COI:** Providing applicable conflict of interest management plans for relying site study teams to the Reviewing IRB  | The **Relying study team** or **Relying IRB** should provide the local UChicago study team and IRB any COI plans.  |
| **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 | The **Relying study team** should provide HSR training certificates to the UChicago study team. The **Relying IRB** should confirm that all individuals engaged in the research at the site have relevant training.  |
| **IRB APPLICATION – STUDYWIDE:** Preparing and submitting the studywide application for initial IRB review and studywide amendments to the Reviewing IRB | The **Lead study team** will submit required IRB submissions.  |
| **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 | The **Relying study team** in conjunction with the Relying IRB are responsible for ensuring local context is addressed in study materials. The **Lead study team** is responsible for providing this information to the Reviewing IRB.  |
| **IRB DETERMINATIONS:** Providing documentation of IRB determinations to relying site study teams | The **Lead study team** should provide IRB determinations to the relying study team. |
| **IRB-APPROVED DOCUMENTS:** Providing copies of IRB-approved materials to the lead study team | The **Reviewing IRB** should provide IRB-approved documents to the lead study team.  |
| **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  | The **Lead study team** should provide the IRB-approved documents to the lead study team |
| **CONSENT FORM TEMPLATE:** Providing the consent form template to relying site study teams | The **Reviewing IRB** in conjunction with the **Lead study team** will provide the consent template to relying site contacts.  |
| **CONSENT FORM LANGUAGE:** Incorporating site specific language into consent form(s) and providing these consent form(s) to the Reviewing IRB | The **Relying study team** in conjunction with the **Relying IRB** should provide the site specific consent to the Lead study team.  |
| **REVIEWING IRB POLICIES:** Providing relevant Reviewing IRB policies to the relying study team  | The **Lead study team** will provide the Reviewing IRB policies to the Relying study team |
| **CONTINUING REVIEW SUBMISSION:** Submitting continuing review progress report to the Reviewing IRB | The **Lead study team** will provide information relevant to continuing review to the Reviewing IRB. The Relying study team should provide this information to the Lead study team.  |
| **REPORTABLE EVENTS:** Reporting reportable events to the Reviewing IRB (e.g., unanticipated problems, noncompliance, subject complaints) | The **Lead study team** should report all required reportable events to the Reviewing IRB. **Relying sites** are responsible for following both the Reviewing IRB reportable event policies and local policies.  |
| **CLOSURE REPORTS:** Providing the Reviewing IRB with required information when a study is closed. | The **Lead study team** should provide closure information the reviewing IRB.  |
| Notes: Click or tap here to enter text. |
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| Local Context Representative/IRB contact |  |
| Title of Local Context Representative/IRB contact |  |
| Contact Email/Telephone of Local Context Representative/IRB Contact |  |
| Attestation by Local Context Representative/ IRB contact | I attest to the accuracy of the responses provided. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_Local Context Representative Signature Date |