**Relying Site Local Context Form**

|  |  |
| --- | --- |
| **Study Title** |  |
| **UChicago Study #** |  |
| **UChicago PI name** |  |

|  |  |
| --- | --- |
| **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 |
| **Does your site have an IRB/HRPP Office (or similar)?** | YES NO  *If YES, provide Point of Contact Information:*  *Name:*  *Email:*  *Phone:*  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 complete all activities described in the protocol or is participation limited to specific activities? | Full protocol Limited protocol  Describe limited protocol activities for this site: |

|  |  |
| --- | --- |
| **Section 2: Regulatory Requirements** | |
| **Describe any local, state, or federal laws or requirements that apply to this study which require consideration for the study as presented:** |  |
| **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?** |  |

|  |  |
| --- | --- |
| **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:* |

|  |  |
| --- | --- |
| **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:* |

|  |  |
| --- | --- |
| **Section 5: Relying Site Principal Investigator Attestation and Signature**  On behalf of the participating site, I confirm that the information provided is accurately reflected in this document. By signing the below, I additionally agree to the following: | |
| I agree to conduct the study in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the overall study/lead UChicago PI, except when necessary to protect the safety, rights, or welfare of subjects.  I agree to personally conduct or supervise the described research as conducted at this relying site.  I agree to inform (as applicable) any potential subject, or any persons used as controls, what activities are research activities and/or standard of care procedures.  I will ensure that the requirements relating to obtaining informed consent approved by the UChicago BSD IRB are followed, as applicable.  I agree to follow UChicago BSD IRB requirements to report promptly reportable events to the overall study/lead UChicago BSD IRB that occur in the course of the research.  I have read and understand the research protocol, including the potential risks of the research.  I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study at the participating site are informed about their obligations in meeting the above commitments.  I agree to maintain adequate and accurate records in accordance with regulatory requirements and to make those records available for inspection by regulatory oversight agencies, including the University of Chicago.  I agree to provide participating site information, including the progress report to the overall study/lead UChicago BSD IRB in a timely manner to comply with continuing review requirements (if applicable) and any other requests related to IRB oversight of the multi-site research.  I agree to promptly report to the overall study/lead UChicago PI all changes in the research activity and all unanticipated problems involving risks to human research participants or others, which would be communicated to the UChicago BSD IRB.  I confirm the work proposed does not involve any data, materials, drugs or devices from a company in which any local members of the study team have a financial interest, or in the case of a corporate sponsor, I have not received any payments, stock or equity from this sponsor in the past 2 years. If any members of the research team have a financial interest, this has been appropriately disclosed and applicable management plan has been provided.  I will not make any changes in the research without prospective UChicago BSD IRB approval, except where necessary to eliminate apparent immediate hazards to human research participants.  I agree to comply with all other requirements regarding the obligations of principal investigators as a participating site PI and all other pertinent requirements that I must adhere to, including local state laws.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Relying Site Principal Investigator Signature Date |