**BSD IRB Local Context Information Form**

**For Relying Sites**

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| **Instructions:** Your site is participating in a study for which the University of Chicago BSD IRB is being asked to serve as the IRB of record. The following information is needed in order for the IRB to conduct its review:* The requirements of any state or local laws, regulations, institutional policies, standards, or other local factors, including site-specific ancillary reviews, relevant to the research, that could affect the conduct or approval at your institution
* Site-specific language for the customizable sections of the informed consent form (ICF) for this study

 This form contains four sections:* Section 1: Institutional Information
* Section 2: Regulatory Requirements
* Section 3: Institutional Requirements & Ancillary Reviews
* Section 4: Community Considerations

Please follow the steps outlined below to complete the form:**Step 1**: (Participating site) Carefully review the protocol and consent form provided by the investigators and complete this site-specific form. *Please Note: It is strongly recommended that the information be completed as a collaborative effort between the PI and local (relying) IRB office.***Step 2**: (Participating site) Review the template consent form and provide any site-specific required language [including any changes to the proposed injury language for your site]. **Step 3**: (UChicago study team) Please upload the following documents into AURA:* Completed copy of this form
* Site-specific consent/HIPAA authorization forms and other site-specific study materials (if any)
* The signed IRB Authorization Agreement or, if using the SMART IRB Agreement, a copy of the SMART IRB Acknowledgment form signed by the relying site’s POC

For questions about this form or process, please contact Millie Maleckar at mmalecka@uchicago.edu, or 773-702-1472.  |

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

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| **Section 1: Institutional Information** –Relying Site |
| **Name of site** |  |
| **Name of site contact person (for the research)** |  |
| **Contact phone number** |  |
| **Contact email** |  |
| **Does your site have a Federalwide Assurance (FWA)?**  | YES[ ]  NO[ ]  *If YES, please complete the following:*FWA #\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*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 the office 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*): |
| **Is your site a covered entity under HIPAA?** | YES[ ]  NO[ ]  Hybrid[ ]  *If Hybrid, does this work fall under the covered component?*YES[ ]  NO[ ]   |
| **Indicate any human subjects protection training course(s) researchers take at your site** (such as CITI, GCP, Local Institution's Training, NIH Protecting Human Research Participants Course, OHRP Training Modules, etc.): |  |
| **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 site-specific information sheet.  |
| **For this study, please indicate whether any study team members at your site have identified a significant financial interest.**  | 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: |

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| **Section 2: Regulatory Requirements*** Identify unique state, local, or federal laws that apply to this study (e.g. legally authorized representatives, state laws regarding confidentiality of specific types of health information, age of emancipated minors)
* Describe any steps that must be taken to adhere to these requirements.
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| **Describe any state, local, or federal laws or requirements that apply to this study which require changes to the study as presented:**  |  |
| **Please outline specific changes to the research based on the requirements identified above:** |  |

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| **Section 3: Institutional Requirements & Ancillary Reviews*** Identify any applicable unique *institutional* requirements & policies which require changes to the study conduct at your site (e.g. recruitment, data security, remuneration, etc.)
* Describe any changes to the study as a result of these requirements. Include changes to the consent form (i.e. consent for future use of data/biospecimens, location, specific injury language, coverage of costs for research-related injuries, HIPAA language, etc.)
* If any changes are required based on ancillary reviews that have not yet been completed at the time this site-specific information sheet is submitted, these changes must be separately communicated to the University of Chicago IRB.
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| **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[ ]   |
| **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[ ]   |
| **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** Describe any local, community, or cultural considerations specific to the targeted subject population, and the site plan to account for the considerations during the conduct of the study.   |
| Are there any special community characteristics/concerns or subject population concerns of which the UChicago IRB should be aware for this study?   | YES[ ]  NO[ ]  Not applicable [ ] *If YES, please describe:* |

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| **Section 5: List of Personnel** Please list all faculty, staff, etc. who will participate in this research study, indicating their role on the study (e.g. title, research activities they will be participating in such as consenting, recruitment, data analysis, etc.), at the local site and confirm that they have met the institutional training requirements for human subjects research.   |
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