**Relying Site SmartIRB Local Context Survey**

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| This form is to be completed by the Relying Institution, to provide key local context information to the Reviewing IRB. A SmartIRB Point of Contact (POC) from the Relying Institution must confirm the accuracy of the information contained within and sign this document. |

**GENERAL INFORMATION**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **1.** | | **Study Title** | | |  |
| **2.** | | **Overall Principal Investigator (PI)** | | |  |
| **3.** | | **Reviewing IRB** | | | Icahn School of Medicine at Mount Sinai |
| **4.** | | **Relying Institution** | | |  |
| **5.** | | **Relying Site Principal Investigator (PI)** | | |  |
|  | | **5a. Relying Site PI Email** | | |  |
|  | | **5b. Relying Site PI Phone number** | | |  |
| **6.** | | **Name of person completing this form** | | |  |
|  | | **6a. Title** | | |  |
|  | | **6b. Email** | | |  |
|  | | **6c. Phone number** | | |  |
| **8.** | | **SmartIRB Agreement Version** | | | Version 1 |
| **9.** | | **Brief description of activities this site will perform (enter "ALL" if this site will perform all procedures in the protocol):** | | | |
| **10a.** | | **Institution’s FWA (Federalwide Assurance):** | | | |
| **10b.** | | **Has the institution’s FWA (Federalwide Assurance) been extended to non-federally funded research?**  **Yes  No** | | | |
| **11.** | | **Provide any other names the site is known by:** | | | |
| **12.** | | **Please identify any affiliations this site has relevant to this study, such as a university, clinic, or hospital. Note: This information is collected to allow us to confirm that all sites engaged in the research are covered by a reliance arrangement and to identify relationships between institutions.** | | | |
|  | | **12a.** | | **If any of the sites identified in question 12 are within a network or system, do they have a separate FWA?**  Yes  No | |
|  | | **12b.** | | If you answered “yes” to question 12a, please identify the sites with the separate FWAs. | |
| **13.** | | **Are there any investigations, audits, or findings (e.g., OHRP, FDA, or local audits) over the past three years that would be relevant to the conduct of new human subjects research proposed at the site?**  Yes  No | | | |
|  | | **13a.** | | **If the answer to question 13 was “yes”, please explain any investigations, audits or findings that may be relevant.** | |
| **14.** | | **This institution is:**  **AAHRPP-accredited**  **CTSA Hub** | | | |
|  | | **14a.** | | **Does the institution have a post approval monitoring program or other regulatory oversight for ongoing research?**  Yes  No | |
|  | | **14b.** | | **If the answer to question 14 was “yes”, does the post approval monitoring program or other regulatory oversight monitor studies that have been deferred to an external IRB?**  Yes  No | |
|  | | **14c.** | | If the answer to question 14a was “yes”, please provide a link (URL) to the post approval monitoring program/regulatory oversight information, or paste information here. | |
|  | |  | |  | |
| **Local Context Information** | | | | | |
| **1.** | **Are there any state laws that the Reviewing IRB will need to consider when reviewing this study?**  Yes  No | | | | |
|  | **1a**. | | **If the answer to question 1 is “yes”, please describe the relevant state laws and provide a link to any key documents (e.g., institutional policy for applying state law or link to the statute).** | | |
| **2.** | **Are there any community or cultural differences for the local population of subjects that require consideration?**  Yes  No | | | | |
|  | **2a.** | | **If the answer to question 2 is “yes”, please describe the relevant information.** | | |
| **3.** | **Is 18 the age of majority for the state in which your site is located?**  Yes  No | | | | |
|  | **3a.** | | **If the answer to question 3 is “no”, please identify the age of majority.** | | |
| **4.** | | **Does the institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects (e.g., the institution does NOT consider this "Preparatory to Research" activities)?**  Yes  No  Not applicable – the HIPAA Privacy Rule does not apply to this study or institution. | | | |
|  | |  | | | |
| **SITE POLICIES** | | | | | |
| **Does the site have a posted policy for any of the following:**  *NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.* | | | | | |
|  | | **Recruitment Policy**  *If selected, please provide a link (URL) to the policy, or paste the relevant policy information below* | | | |
|  | | **Age of Assent Policy**  *If selected, please provide a link (URL) to the policy, or paste the relevant policy information below* | | | |
|  | | **Consent Process for those with Impaired Decision-Making Capacity**  *If selected, please provide a link (URL) to the policy, or paste the relevant policy information below* | | | |
|  | | **Use of Short Forms for Non-English Speaking Individuals**  *If selected, please provide a link (URL) to the policy, or paste the relevant policy information below* | | | |
|  | | **Translation of Consent Forms for Non-English Speaking Individuals**  *If selected, please provide a link (URL) to the policy, or paste the relevant policy information below* | | | |
|  | | **Any other site-specific policies that the Reviewing IRB should consider with regards to this study.**  *If selected, please provide a link (URL) to the policy, or paste the relevant policy information below* | | | |
| **1.** | | **Please provide any institutionally-required consent form language for compensation in the event of research-related injury:** | | | |
| **2.** | | **Please provide any other consent form language required by site policy or state law:** | | | |
| **3.** | | **Please review the planned list of personnel who will be engaged in human subjects research at your institution and verify that all of your institutionally-required training for the conduct of the research [including human subjects protections training, GCP training, and HIPAA training, as applicable] has been completed for each individual.**  I confirm that the planned list of personnel who will be engaged in human subjects research at my institution have completed the institutionally-required training for the conduct of human subject research.  If you cannot confirm, please explain: | | | |
| **4.** | | **Are all involved individuals from your institution credentialed and/or appropriately qualified and meet the institution's standards for eligibility to conduct the research as described in the approved protocol?**  I confirm that all involved individuals are 1) credentialed and/or appropriately qualified and 2) meet the institution’s standards for eligibility to conduct the research as described in the approved protocol.  If you cannot confirm, please explain: | | | |
| **5.** | | **Did the institution determine there is a relevant individual or institutional financial COI for this protocol? If so, please provide a copy of the COI Management Plan.**  The institution determined that there are no relevant individual or institutional financial COIs for this protocol.  The institution determined that there is a relevant individual and/or institutional financial COI for this protocol. The COI Management Plan has been provided to the Reviewing IRB. | | | |
| **6.** | | **Please identify any ancillary reviews required at your site [e.g. radiation safety review, review for research with biospecimens, etc.] that will be required before the study may be initiated at your site. Please also indicate if any of those reviews may impact the IRB review and whether they are completed.** | | | |
| **7.** | | **Please provide any other information that the Reviewing IRB needs to know/consider that has not yet been provided:** | | | |

**Relying (Local) Site PI:**

Name (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sign: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**SmartIRB Point of Contact who confirmed the accuracy of the information provided in this form:**

Name (Print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Sign: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_