Local Context Survey

This survey is intended for use when LSUHSC-NO will be the IRB of Record for external sites (Relying Institutions) in a multi-center study **AND** the reliance is not being implemented through the SMART IRB or IREx platforms. The LSUHSC lead study team will distribute this survey to Relying Institution study teams to gather information about particular regulatory and/or institutional requirements. The completed surveys should be submitted by the lead study team to the LSUHSC IRB, along with additional required documents, including a fully executed reliance agreement, as either part of an initial protocol application or as an amendment to an approved protocol.

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| **SECTION I: INSTITUTION & HRPP INFORMATION** |
| **Institution** |       |
| **FWA Number** |       | **FWA Expiration Date:** |       |
| **IRB Registration Number** |       | **IORG Number** |       |
| **Quality Control Mechanism**  | [ ]  AAHRPP Accredited  | [ ]  Established QA/QI Program  |
| [ ]  OHRP IRB Self-Assessment  | [ ]  Other  |
| If other, describe:       |
| Status: | Date of most recent review:       |
| **IRB Points of Contact** | *IRB Staff member(s) who will serve as points of contacts for this institution* |
| **Name:** |       | **Name:** |       |
| **Role:** |       | **Role:** |       |
| **Phone:** |       | **Phone:** |       |
| **Email:** |       | **Email:** |       |
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| **SECTION II: STUDY INFORMATION** |
| **LSUHSC IRB Number** (if known) |       |
| **Study Title** |       |
| **Short Title** |       |
| **Study Personnel at Relying Site** | **Principal Investigator** | **Primary Contact** |
| **Name:** |       | **Name:** |       |
| **Phone:** |       | **Phone:** |       |
| **Email:** |       | **Email:** |       |
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| **SECTION III: RELYING INSTITUTION OVERSIGHT** |
| **Institutional Approvals & Ancillary Reviews** | *The Relying Institution is responsible for assuring that any required institution approvals and ancillary reviews (e.g., radiation safety, pharmacy) that apply to the conduct of this research study are performed.***Check one:**[ ]  All required department and/or ancillary reviews **have been** conducted per Relying Institution policies and procedures.[ ]  All required department and ancillary reviews **are in process** per Relying Institution policies and procedures, and the research will not begin until all required reviews are completed. |
| **Conflicts of Interest**  | *The Relying Institution is responsible for identifying and reviewing any conflicts of interest in accordance with their institutional policies. It is the Relying Institution's responsibility to manage or eliminate any conflict.***Do any of the investigators involved in the design, conduct, or reporting of the research (or their immediate families) have a financial interest related to the research?** [ ]  No[ ]  YesIf “Yes,” attach the conflict of interest management plan for each applicable investigator and any institution-specific COI language required for consent form(s):       |
| **Human Subjects Protection Training** | *The Relying Institution must ensure that all investigators and research staff undergo training on the ethics and regulations of human subject* *protections before being involved in the conduct of this research. For applicable clinical research, the Relying Institution must ensure that all investigators and research staff undergo training on Good Clinical Practice (GCP).***Check one:**[ ]  All investigators and research staff involved with the conduct of this research have taken one or more of the training programs listed below. [ ]  Some investigators and research staff involved with the conduct of this research are in the process of completing the required training. The research will not begin until all research personnel have completed the required trainings.Human research protection training programs accepted at the Relying Institution include *(Check all that apply)*:[ ]  Collaborative IRB Training Initiative (CITI)[ ]  ACRP Certified Clinical Investigator Training[ ]  CenterWatch: Protecting Study Volunteers in Research[ ]  DIA Certified Investigator (CCI)[ ]  SOCRA Clinical Research Professional (CRP)[ ]  Other; describe:       |
| **Qualifications of Investigators** | Beyond the above, state the qualifications of the PI to conduct and supervise the proposed research:       |
| Beyond the above, state the training and experience of the PIspecifically related to the proposed research:       |
| **Adequacy of Research Site** | [ ]  Please check here to verify that the Relying Site has adequate resources to execute the proposed protocol (e.g. facilities, equipment and staff are adequate). |
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| **SECTION IV: LOCAL CONSIDERATION/CONTEXT INFORMATION** |
| 1. **Are there any governmental inquiries or investigations over the past three years that may be material to the activities that would be conducted under this research protocol, including research compliance problems (e.g., OHRP or FDA inquiries or investigations and corrective actions)?**

[ ]  Yes [ ]  No*If yes, provide the nature of the inquiries or investigations, the status of such matters, including how they were resolved (if resolved):*       |
| 1. **Are there any state or local laws that need to be considered that would impact this research protocol or informed consent document (*e.g.*, wards of state, emancipated minors, results of pregnancy testing)?**

[ ]  Yes [ ]  No*If “Yes” please describe:*  |
| 1. **Provide the age of majority In your jurisdiction(s) for this research protocol:**
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| 1. **Are there any local, community or cultural issues that may be different for your population of subjects for this research protocol that require consideration?**

[ ]  Yes [ ]  No*If “Yes” please describe:*       |
| 1. **Are there any special characteristics of your institution or community of which the LSUHSC-NO IRB should be made aware?**

[ ]  Yes [ ]  No*If Yes, please describe:*       |
| 1. **Please provide any Institution-specific consent language that must be included in consent forms used at the Relying Institution (*e.g.*, logo; coverage of research injury; costs to participants; required phone numbers for the study doctor, and a person unaffiliated with the study, such as the local IRB).** *Please do not provide a general template consent document. The LSUHSC-NO IRB will require the Relying Institution PI to incorporate any required consent language for the consent form. If any language differs from what appears here, the Institution PI will be asked to revise it.*

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| 1. **Do you expect a large percentage of the potential research population to speak language(s) other than English?**

[ ]  Yes [ ]  No*If “Yes”, state the language(s):*      |
| 1. **Does your site approve of the use of short forms for non-English speaking individuals for this research protocol?**

[ ]  N/A[ ]  Yes; provide or describe the short form to be used, and any requirement for translation of the long consent form:      [ ]  No; describe the requirements for consenting subjects that do not read or speak English:       |
| 1. **If applicable to this study, please describe any institutional policies and procedures or generally-accepted ways you operationalize obtaining assent of children for participation in research.**

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| 1. **If applicable to this study, please describe any institutional policies and procedures or generally-accepted ways you operationalize obtaining surrogate consent for adult individuals with impaired decision-making capacity.**

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| 1. **The LSUHSC IRB will make determinations for full or partial waivers of HIPAA authorization (when** **requested) and/or determine when written HIPAA authorization is required. At LSUHSC, consentand HIPAA Authorization are separate forms.**

**The Relying Institution (check one):**[ ]  Prefers HIPAA research authorization language to be **embedded** in the consent form(s). *Provide the required language:*      [ ]  Requires a separate HIPAA research authorization to be used. *Provide the HIPAA research authorization to be used.* |
| 1. **If applicable to this study, please provide any site-specific content or procedural information regarding the recruitment process.**

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| 1. **Please describe the plan by which the Relying Institution and/or Relying Study Team will communicate with the LSUHSC-NO IRB and /or the Lead Study Team.** *The plan should identify individuals or their positions; the type(s) of information (e.g., pre-approval information or documents, IRB determinations and approved documents, Reportable New Information) they are responsible for submitting to, or receiving from, LSUHSC-NO; and the communication methods.*

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| 1. **Is there anything else described in this research protocol that would not fall within the policies and practices of your institution that the LSUHSC-NO IRB needs to be aware of for review of this research?**

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| **SECTION V: SITE DOCUMENTS** |
| **Please provide the following documents, if applicable, and when available:*** COI management plan(s);
* Written materials to be provided to or meant to be seen or heard by subjects at your site:
* Evaluation instruments and surveys;
* Advertisements (printed, audio, and video);
* Recruitment materials and scripts ;
* All consenting/assenting documents with the following local site statements, as applicable, inserted using tracked changes:
* Statement regarding the availability of treatment for research-related injury
* Statement regarding compensation for research-related injury
* Statement regarding payment/reimbursement of research costs incurred by subjects
* Any HIPAA language to be embedded in the consenting forms
* If consent will not be documented in writing, a script of information to be provided to subjects;
* Foreign language versions of the consent/assent documents;
* Stand-alone HIPAA Authorization form;
* Local study team contact information.
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| **SECTION VI: ATTESTATIONS** |
| **INVESTIGATOR ATTESTATION** |
| *I will conduct this study in accordance with LSUHSC-NO IRB, and all relevant local Institution, requirements.* |
| **Signature of Relying Institution Investigator:** | **Date:** |
| **RELYING INSTITUTION ATTESTATION** |
| *The information provided is accurate and represents current Institutional information that the LSUHSC-NO IRB may consider in order to serve as IRB of Record for the Relying Site.* |
| **Signature of Authorized IRB Official of the Relying Institution:** | **Date:** |
| **Typed Name:**  |
| **Email Address:**  |
| **Telephone Number:**  |