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| **The purpose of this form is to provide CHLA with information about the Institution that will rely upon CHLA for IRB review and oversight. This form needs to be signed by the Institution PI and an authorized individual from the Institution’s regulatory (IRB) office.**  |
| **CHLA Protocol # (**if known**):** | Click or tap here to enter text. |
| **Name of the Study Protocol:** | Click or tap here to enter text. |
| **Institution Requesting Reliance on CHLA:** | **Name of Institution:** Click or tap here to enter text.**FWA#:** Click or tap here to enter text.**Name of Institutional Official (IO):** Click or tap here to enter text.**IO Email Address:** Click or tap here to enter text. |
| **Name of PI at the Relying Institution:** | **Name:** Click or tap here to enter text.**Phone:** Click or tap here to enter text.**Email:** Click or tap here to enter text. |
| **Study Team Contact Person (optional):** | **Name:** Click or tap here to enter text.**Phone:** Click or tap here to enter text.**Email:** Click or tap here to enter text. |
| **Institution Approvals and Ancillary Reviews** * The Relying Institution is responsible for assuring that any required Institution approvals and ancillary reviews (e.g., radiation safety committee) are performed that apply to the conduct of this research study.
 | **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.  |
| **Local Context Information*** Provide details of any Institution specific local context issues pertaining to this study, such as:
	+ State laws
	+ Institutional policies
	+ Age of majority
	+ Consent requirements for children
	+ Local, community or culture issues
 | Click or tap here to enter text. |
| **Investigator 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 clinical research, the Relying Institution must ensure that all investigators and research staff undergo training on Good Clinical Practice (GCP).
 | **All investigators and research staff involved with the conduct of this research have taken one or more of the following training programs.** **Check all that apply:**[ ]  Collaborative IRB Training Initiative (CITI)[ ]  Other Institution Specific Training (*describe*): Click or tap here to enter text.[ ]  ACRP Certified Clinical Investigator Training[ ]  CenterWatch: Protecting Study Volunteers in Research[ ]  DIA Certified Investigator (CCI)[ ]  SOCRA Clinical Research Professional (CRP) |
| **Conflicts of Interest:** * The Relying Institution is responsible for identifying and reviewing any conflicts of interest in accordance with their institutional policies.
 | **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**[ ]  **Yes –** Provide the conflict of interest management plan and any Institution specific COI language required for consent forms(s). Click or tap here to enter text. |
| **Consent Form Language*** Provide any Institution consent language that must be included in consent forms used at this Institution (e.g., coverage of research injury, 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 from the Institution.
* NOTE: The CHLA IRB will require the 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.
 | Click or tap here to enter text. |
| **Short Form Consent*** The CHLA IRB allows the use of a short form consent process with subjects that do not read or speak English. Does the Institution allow the use of a short form consent process?
 | **Check one:**[ ]  **Yes** - Provide or describe the short form to be used, and any requirement for translation of the long consent form: Click or tap here to enter text.[ ]  **No** - Describe the requirements for consenting subjects that do not read or speak English: Click or tap here to enter text. |
| **HIPAA*** The CHLA IRB will make determinations for full or partial waivers of HIPAA authorization (when requested) and/or determine when written HIPAA authorization is required.
* Provide the Institution specific language for the consent form(s).
 | **Check one:**[ ]  This Institution allows **embedded** HIPAA research authorization language to be included in the consent form(s). Provide the required language: Click or tap here to enter text.[ ]  This Institution requires a **separate** HIPAA research authorization to be used. Provide the HIPAA research authorization to be used. |

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| **Investigator Attestation** |
| **I will conduct this study in accordance with the CHLA IRB requirements and all relevant local Institution requirements.**  |
| **Relying Institution Investigator Signature** | **Date** |
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| **Institution Attestation** |
| The information provided in this form is accurate and represents current Institutional information that the CHLA IRB will consider as the IRB of Record for the Relying Site. |
| **Authorized IRB (Regulatory) Official of the Relying Institution Signature** | **Date** |
|  |  |
| **Typed Name:** Click or tap here to enter text. |
| **Email Address:** Click or tap here to enter text. |
| **Telephone Number:** Click or tap here to enter text. |