Research Conducted at Multiple Sites with KSU as IRB of Record

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| **INSTRUCTIONS for KSU PI and INVESTIGATORS:** |
| 1. Work with the external institution to complete the information and include it
2. Upload this Local Context Form to the IRB submission.
3. NO SITE MAY BEGIN data collection prior to receiving notification from the KSU IRB that your application has been fully approved.

**DEFINITIONS*****Engaged in Research -*** *An institution is considered* engaged *in research when its employees or agents for the purposes of the research project obtain: (1) data about the subjects of the research through intervention or interaction with them; (2) identifiable private information about the subjects of the research; or (3) the informed consent of human subjects for the research.****IRB of Record/Reviewing IRB –*** *The IRB responsible for review of research and for determining that the research meets the regulatory requirements for approval.* ***Local Context/Local Consideration –*** *An aspect about the Relying institution which could affect the Review IRB’s determination, including criteria for IRB Approval.* ***Performance Site –*** *a site whose staff, facilities or private records of individuals are engaged in the conduct of research; or a site that receives HHS funds. The performance site is the actual place where the research activity (e.g.,site where staff are consenting subjects).****Relying IRB –*** *The IRB ceding responsibility for review of research.* |

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| **Section I - KSU Investigator Information** |
| Last Name: Click or tap here to enter text. First Name: Click or tap here to enter text. |
| Title of Study (should match Human Subjects Research Application) |
| Click or tap here to enter text. |
| **Section II - Relying Site Information**  |
| 1. **Relying Site Details**
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| 1. Name of Relying Site:
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| Click or tap here to enter text. |
| 1. Name of Lead Investigator at the Relying Site:
 |
|  Click or tap here to enter text. |
| 1. Does the relying site have an institutional IRB?

 [ ]  Yes [ ]  NoIf yes, provide the IRB Contact information:  |
| Point of Contact Name & Title: Click or tap here to enter text. Point of Contact Phone Number: Click or tap here to enter text.Point of Contact Email: Click or tap here to enter text. |
| 1. Identify the type of agreement

[ ]  Institutional Authorization Agreement[ ]  SMART IRB[ ]  Executed Master Agreement |
| 1. Describe all study procedures that the Relying Site will engage in (e.g., recruitment procedures, conduct research interviews; obtain informed consent, accessing records)?

Click or tap here to enter text. |
| 1. **Relying Site Requirements (Completed by Site’s IRB Contact)**
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| 1. Describe local or state laws that the KSU IRB should consider when reviewing this site (e.g. privacy, age of majority, LAR requirements etc.)
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| Click or tap here to enter text. |
| 1. Provide any institutional policies that the KSU IRB may need to consider when reviewing this Site.

Click or tap here to enter text. |
| 1. Describe any customs, beliefs, values or practices of distinct subject populations that you may expect to be enrolled or included in this study and that should be considered by the KSU IRB.

Click or tap here to enter text. |
| 1. Do you verify that all site personnel engaged in research are appropriately qualified and up-to-date on your site’s institutionally-required training?

[ ]  Yes [ ]  No |
| 1. Is there an individual or institutional financial conflict of interest for this study?

[ ]  Yes, conflict eliminated[ ]  Yes, management plan attached[ ]  No [ ]  Not Applicable for this study |
| 1. HIPAA Determinations & Actions
	1. Is your site a HIPAA Covered Entity? [ ]  Yes [ ]  No [ ]  Not applicable for this study
	2. If yes, do you elect for the KSU IRB to make HIPAA determinations or perform any HIPAA actions or will your site? [ ]  KSU [ ]  Relying Site [ ]  Not applicable for this study
	3. Required authorization language should be attached to this form. [ ]  None [ ]  Attached [ ]  Not applicable
 |
| 1. **Signature**
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