

## PROJECTS CEDING REVIEW TO UH AS THE IRB OF RECORD: LOCAL CONTEXT INFORMATION SHEET

The purpose of this form is to facilitate centralized review of research and provide the UH IRB with local context information necessary for the review of the research. One form is required for each site located outside of Texas. Local Site PI or Local Site refers to the site that will rely on the UH IRB for review of the research **INFORMATION REVIEW PROCESS** The Local Site must complete this form, obtain the required signature from the Local Site PI and submit the completed form to the UH PI. The UH PI will collect these forms and attach them to the Icon protocol submission, as well as keep a copy of this form in the UH PI's files. **UH PRINCIPAL INVESTIGATOR: Project Title: Funding Agency:** Grant number: LOCAL SITE (RELYING) PRINCIPAL INVESTIGATOR: **First Name** Middle **Last Name** Degree **Email** Phone Initial Institution name: City, State, Country: 1. Have any of the Local Site investigators reported a financial conflict of interest related to this study that resulted in a management plan? Yes □ No If Yes, please attach the Local Site's institutionally-approved COI management plan with this form when

sending to the UH PI.
Note to UH PI: The site's institutionally-approved COI management plan will need to be attached to the Icon
protocol.
2. Describe how the Local Site investigators will identify and recruit potential study participants.
N/A  3. Will the conduct of the study at the Local Site differ in any way from the full protocol? If so, please explain
N/A
4. Based on the location of the research site, if children/minors are being recruited, are there any state or local laws that need to be considered that would impact minors in this research protocol (wards of state, emancipated minors, results of pregnant testing?
N/A
5. Please indicate the age of majority in the Country or State of the Local Site:

6. Are there any local, community or cultural issues pertaining to the Local Site that may require consideration by the UH IRB?
No
7. Is it reasonably expected that a percentage of the potential research population to be recruited at the Local Site will primarily speak/read languages other than English?
If so, please indicate the languages:
N/A Yes No
8. Does the Local Site's IRB accept the use of short forms for non English speaking individuals?
If Yes: Are there any limitations on the use of short forms (i.e only minimal risk research)? If so, please explain.
9. Please specify any state or local laws that affect the use of legally authorized representatives in providing consent on behalf of an adult individual with impaired decision-making capacity:
N/A

10. Does the Local Site require the use of institution-specific HIPAA language or authorization templates? If yes, please explain here (or attach to this form):
N/A
11. Will consent form(s)/assent form(s) need to be individualized for the Relying Site to include conflict of
interest disclosures or specific research injury language? If so, please describe:
N/A
Oversight and Reporting
I understand and agree to the following statements:
Any potential unanticipated problems involving risks to subjects or others will be reported promptly to
the UH IRB
Any potential noncompliance with the protocol or IRB requirements will be reported promptly to the UH IRB
Should a conflict of interest requiring management be determined by the Local Site, the management plan will be promptly provided to the UH IRB
Printed Name of Relying Site PI
Signature of Relying Site PI
<del></del>
Date