University of Hawaii – Human Studies Program (HSP) – Local Context Form

Name of person completing form: Click or tap here to enter text. email:

Title of person: Click or tap here to enter text.

HSP Protocol # (if available):

Protocol Title: Click or tap here to enter text.

UH Principal Investigator:       email:

|  |  |
| --- | --- |
|  | Relying Site Name:       |
|  | Relying Site Protocol #:       |
|  | Relying Site Investigator Name:       | Email:       |
|  |  |
|  | Is your institution a covered entity under HIPAA for research activities?       |
|  | If yes, what are your institutions HIPAA authorization/informed consent document requirements? |
|  | [ ]  | Stand Alone HIPAA authorization required |
|  | [ ]  | Combined HIPAA authorization acceptable |
|  | [ ]  | Combined or stand alone HIPAA authorization acceptable |
|  | 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)?       |
|  | If applicable, provide any institution-specific details regarding HIPAA activities that may be relevant to the reviewing IRB:       |
|  | Are all relying site research team investigators in compliance with required training and qualification requirements (CITI or equivalent human subjects ethics training)?       |
|  | Do all individuals at the relying institution involved with this protocol meet the institutions standards for eligibility to conduct research?       |
|  | Has any institutional or financial conflict of interest been reported at the relying institution, with regard to this protocol? If yes, please attach the Conflict of Interest Management Plan.       |
|  | Local Institutional Ancillary Review requirements at relying site. If required, please attach review approvals and/or relevant documentation. [ ]  N/A      |
|  | What is the age of majority in your state? [ ]  N/A      |
|  | What is your institution’s interpretation of state law regarding when minors in your state may consent for themselves, for the purposes of participation in research? [ ]  N/A      |
|  | Are there any other state laws that the Reviewing IRB will need to consider when reviewing this study? [ ]  N/A       |
|  | Are there any Institutional Policies that pertain to this protocol? [ ]  N/A       |
|  | Is there any institutionally-required consent form language? Please attach. [ ]  N/A       |
|  | Are there any community or cultural differences for the local population of subjects that require consideration? [ ]  N/A       |
|  | Are there any changes required to the study plan related to the available resources at your site?[ ]  N/A       |