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| --- | --- |
| The purpose of this checklist is to provide support for PIs and study personnel when submitting a local context review application for IRB Review when review for a study is ceded to another IRB. This checklist must be used for all local context reviews and this checklist must be included in the submission. For full details on local context review, see **SOP – Local Context Review**. | |
| **Study Name:**  **Primary Investigator:**  **Entity:** |  |
|  | |
| **Each local context review submission must include the following items/forms:** | |
|  | |
|  | Cover Letter |
|  | Study Personnel List |
|  | Site PI CV |
|  | CITI Training (for each local member of study personnel) |
|  | Conflict of Interest (for each local member of study personnel) |
|  | Confidentiality Agreements (for each local member of study personnel) |
|  | |
| **Each local review submission must include the following items for ceded IRB review:** | |
|  | |
|  | Feasibility Review (attach) |
|  | Local ICF language (attach) |
|  | Funding (attach, if applicable) |
|  | |
| **Does the study involve any of the following special procedures or considerations?** | |
|  | |
| **The study team may enroll subjects with impaired decision-making capacity.**  *If selected,* *describe below how the study team will verify someone is**qualified to be the**potential subject’s Legally*  *Authorized Representative.* | Yes |
| **The study team may enroll wards of the state (e.g., foster children).** | Yes |
| **The study team may enroll prisoners.**  *If selected, describe below how the study team will verify someone is qualified to be the potential subject’s Legally Authorized Representative.* | Yes |
| **The study involves a drug, biologic, and/or device. If so, describe:**  **a) the specific location where study drugs/devices/biologics will be stored**  **b) how storage location will be secured**  **c) who is responsible for study drug or biologic preparation**  **d) who will dispense subject drug or biologic to the subject** | Yes |
|  | |
| **Site-Specific Study Protocol Differences (All sections must be completed)** | |
|  | |
| 1. **Describe any differences between what is stated in the main protocol and what activities will or will not be conducted at your site (e.g., Arm B of the protocol will not be conducted at our site)** |  |
| 1. **Describe how and when people will be recruited to participate in the study.** *Specify who and how investigators will be involved in recruitment and the consent process. Explain how people will be approached, what recruitment material will be used (flyers, internet, letters, phone screening scripts), and how long the person has to decide to participate.* |  |
| 1. **Describe the consent process (include who conducts the process and where).** |  |
| 1. **How many subjects do you intend to enroll at your site?** |  |
| 1. **Will medical records be accessed prior to written consent, or with a waiver of consent?** | Yes  No  Not applicable – no medical records will be accessed for this study |
| 1. **If yes to 5, describe how the study team will access the records.** |  |
| 1. **How and where will data (e.g., electronic, paper, audio) be stored at your site? If there is no storage of data locally, describe data storage plan of the study.** |  |
| 1. **Who will have access to study data?** |  |
| 1. **How is subject confidentiality protected?** |  |
|  | |
| **Local Context Information** | |
|  | |
| 1. **Are there any state laws that the LRH IRB will need to consider when reviewing this study?** | Yes  No |
| 1. **If the answer to question 1 is “yes”, please describe the relevant state laws and provide a link to any key documents (e.g., institutional policy for applying state law or link to the statute).** |  |
| 1. **Are there any community or cultural differences for the local population of subjects that require consideration?** | Yes  No |
| 1. **If the answer to question 3 is “yes”, please describe the relevant information.** |  |
| Notes: | |
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PI or Study Team Signature: Date:

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