Form Inst-H

Local **Sponsor**-Investigator Monitoring Plan

*Complete this form if a local investigator is listed as the sponsor on an FDA issued IND or IDE*

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| UTHSCSA Tracking Number |

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| **Item 1**  **Sponsor/PI Training Requirements\*** | \* Good Clinical Practice For IND/IDE Holders  \* Human Subjects training (CITI or equivalent)  \* Principal Investigator/Sponsor CV  Specialized study training, if applicable  Number of studies in which you have served in the role of Sponsor Investigator:  None  1-3  3 or more |

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| **Item 2**  **Sponsor Requirements** | \* Monitor Assigned  Monitor Identified:  Yes No, OCR Monitoring required (link to Monitoring Plan)\*  If yes checked, Monitor name:  \* Monitor Qualification and training:  Yes N/A  SOP for reporting IND or IDE changes to FDA  SOP for providing all reports, updates and adverse events to FDA as required  \* Registration and timely reporting of Applicable Clinical Trials in ClinicalTrials.gov  N/A, non-NIH funded pilot study  Registration complete, NCT#  Registration pending  For Multi-site studies: SOP for ensuring compliance of other sites in reporting to Local Sponsor |

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| **Item 3**  **FDA Documentation Requirements** | **Drugs or Biologics:** | Completed | Pending | N/A |
| Form 1571 (IND Application) |  |  |  |
| Form 1572 (Statement of Investigator) |  |  |  |
| Form 3674 (Certification of Compliance) |  |  |  |
| All FDA correspondence sent in addition to 30 day acknowledgement letter receipt from FDA |  |  |  |
| **Devices:** | Completed | Pending | N/A |
| IDE Application Letter |  |  |  |
| IDE Approval Letter/email communication |  |  |  |
| All FDA correspondence sent in addition to 30 day acknowledgement letter receipt from FDA |  |  |  |

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| **Item 4**  **Investigational Product Information** | **Source:**  From hospital/commercial pharmacy stock -  From a compounding pharmacy -  Manufactured locally by investigator/study staff  Other  **Storage:**  Hospital Pharmacy  Approved OCR location  Location which requires OCR approval  Exempt from storage requirements |

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| **Item 5**  **Supporting sponsor documents \*** *Must be finalized prior to Site Initiation Visit*  *(Link to Local Sponsor Investigator Toolkit)* | YES | NO | N/A | Reason, if N/A |
| Case Report Forms (CRFs) |  |  |  |  |
| Monitoring Checklist/ Documentation |  |  |  |  |
| Drug Accountability Log |  |  |  |  |
| Delegation of Tasks Log |  |  |  |  |
| Other: |  |  |  |  |