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 applicableNumber 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 AssignedMonitor 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:       | [ ]  | [ ]  | [ ]  |       |