LSUHSC-NO HUMAN RESEARCH PROTECTION PROGRAM

POST-APPROVAL MONITORING AND EDUCATION SELF-ASSESSMENT TOOL

In addition to continuing review of projects, either annually or tri-annually, and other action items submitted for IRB review (e.g., SAEs, unanticipated problems, amendments, etc.), the IRB and Office of Compliance Programs (OCP) conduct a formal post-approval monitoring (PAM) program to assure compliance with all aspects of the research study. This program includes study self-assessments, non-directed (random) audits conducted by OCP and the Human Research Protection Program (HRPP), and directed for-cause audits. All study-related materials including, but not limited to, Case Report Forms, regulatory documents, communication with the sponsor, signed informed consent documents, and source documents must be made available to the IRB for audits.

The PAM self-assessment is an exercise to assist the IRB in the review of the internal quality assurance practices of Investigators. This self-evaluation should also assist investigators in monitoring and improving practices and processes regarding their studies. Based on the results of this process, studies may be selected for non-directed or directed audits (based on suspected non-compliance issues). Please refer to the [LSUHSC HRPP Policies & Procedures](https://www.lsuhsc.edu/administration/academic/ors/policies_procedures.aspx) for more information about the PAM process.

**Instructions:** Please respond to all applicable questions and return the completed form to the IRB by the deadline provided in the request. Supplemental documentation may be submitted with the completed form. If a compliance issue is identified upon the completion of the self-evaluation tool, please refer to [LSUHSC HRPP Policies & Procedures](https://www.lsuhsc.edu/administration/academic/ors/policies_procedures.aspx) for appropriate reporting procedures.

**GENERAL STUDY INFORMATION**

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| **Study Title:** | Click or tap here to enter text. |
| **IRB #:**  | Click or tap here to enter text. |
| **Funding Source:**  | [ ]  Industry – Click or tap here to enter text.[ ]  Federal – Click or tap here to enter text.[ ]  Internal/Departmental[ ]  Unfunded[ ]  Other: Click or tap here to enter text. |
| **Principal Investigator’s Information:**  | Name: Click or tap here to enter text.Campus Address: Click or tap here to enter text.Email: Click or tap here to enter text.Phone Number: Click or tap here to enter text. |
| **Contact Study Coordinator Information:**  | Name: Click or tap here to enter text.Campus Address: Click or tap here to enter text.Email: Click or tap here to enter text.Phone Number: Click or tap here to enter text. |
| **Person Completing This Form:**  | Name: Click or tap here to enter text.Role: Click or tap here to enter text. |

**PRINCIPAL INVESTIGATOR’S CERTIFICATION**

The Principal Investigator acknowledges that he/she is responsible for the overall conduct of the study and certifies that the information in this assessment is complete and accurate to the best of his/her knowledge.

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Signature of the Principal Investigator Date

**PERFORMANCE SITES AND STUDY POPULATION**

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| Please list all sites where research activities are taking place: | Click or tap here to enter text. |
| Were all external institutional approvals secured prior to initiation of the study? (*check all that apply*) | [ ]  UMC RRC[ ]  Children’s Hospital [ ]  Tulane[ ]  Ochsner[ ]  Woman’s Hospital[ ]  Our Lady of the Lake[ ]  West Jefferson [ ]  Other: Click or tap here to enter text. |
| Please indicate if any of the following study populations are represented by participants you have enrolled:  | [ ]  Children[ ]  Pregnant Women, Fetuses, or Neonates[ ]  Prisoners[ ]  LSUHSC Faculty/Staff or Students[ ]  Individuals with impaired decision making capacity [ ]  Economically or educationally disadvantaged individuals [ ]  Institutionalized Individuals [ ]  Undocumented Immigrants[ ]  None of the Above  |

**REGULATORY DOCUMENTATION**

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| **Protocol** | **Yes** | **No** |
| 1 | Is the most recent version of the protocol saved in a study binder (paper, electronic, or both)?  |[ ] [ ]
| 2 | Are there previous versions of the protocol? *If no, skip to* ***FDA-Regulated…*** |[ ] [ ]
| 3 | Are the previous versions saved in a study binder (paper, electronic, or both)?  |[ ] [ ]
| 4 | Is the version # and version date included on each document?  |[ ] [ ]

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| **FDA-Regulated Research** | **Yes** | **No** |
| 1 | Is this an FDA-regulated study? *If no, skip to* ***Federally Funded Research*** |[ ] [ ]
| 2 | Is there a signed 1572 saved in a study binder (paper, electronic, or both)?  |[ ] [ ]
| 3 | Has a copy of the 1572 been provided to the IRB? |[ ] [ ]
| 4 | Is the Clinical Investigator Financial Disclosure form (FDA 3455 or 3454) for each investigator saved in a study binder (paper, electronic, or both)?  |[ ] [ ]
| 5 | Is all the correspondence to and from the sponsor saved in a study binder (paper, electronic, or both)?  |[ ] [ ]

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| **Federally Funded Research** | **Yes** | **No** |
| 1 | Is this research activity federally funded or submitted for federal funding? *If no, skip to* ***Investigator-Initiated Research*** |[ ] [ ]
| 2 | Is the protocol as originally submitted to the IRB congruent with the application submitted for federal funding?  |[ ] [ ]

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| **Investigator-Initiated Research** | **Yes** | **No** |
| 1 | Is this research investigator initiated? *If no, skip to* ***Training and Experience*** |[ ] [ ]
| 2 | The PI is the holder of an:  | [ ]  IND[ ]  IDE (*skip to* ***Training and Experience****)*[ ]  None (*skip to* ***Training and Experience****)* |
| 3 | Is there a signed copy of the 1571 saved in a study binder (paper, electronic, or both)? |[ ] [ ]
| 4 | Has a copy of the 1571 been submitted to the IRB?  |[ ] [ ]
| 5 | Was a copy of the 1571 included in any submissions of the following to the FDA? Original SubmissionAll AmendmentsSafety Reports and Annual Reports |  |  |
|  |  |[ ] [ ]
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| **Training and Experience**  |
| 1 | Please list all current study personnel and their role: (*add lines as needed)* |
|  | **Personnel Name** | **Role** |
|  | Click or tap here to enter text. | Click or tap here to enter text. |
|  | Click or tap here to enter text. | Click or tap here to enter text. |
|  | Click or tap here to enter text. | Click or tap here to enter text. |
|  | Click or tap here to enter text. | Click or tap here to enter text. |
|  | **Yes** | **No** |
| 2 | Is the study being conducted in a clinical in-patient or outpatient unit?If yes, has the unit staff been informed/trained on the protocol? |[ ] [ ]
|  |  |[ ] [ ]
| 3 | Does the PI and study personnel continue to have the time and resources available to do the work? |[ ] [ ]
| 4 | Study Personnel meetings are conducted:  | [ ]  Weekly [ ]  Monthly[ ]  Quarterly[ ]  Other: Click or tap here to enter text.[ ]  Not Applicable |

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| **Enrollment**  | **Yes** | **No** |
| 1 | Is there a subject enrollment log? *If no, skip to* ***Monitoring*** |[ ] [ ]
| 2 | Is the subject enrollment log up to date? |[ ] [ ]

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| **Monitoring**  | **Yes** | **No** |
| 1 | Is the study site externally monitored by sponsor or data safety monitoring board? *If no, skip to* ***Staff Signature Log*** |[ ] [ ]
| 2 | Is there a monitoring log? *If no, skip to* ***Staff Signature Log***  |[ ] [ ]
| 3 | Is the monitoring log up to date?  |[ ] [ ]
| 4 | How frequently is the site monitored? | Click or tap here to enter text. |
| 5 | Name of monitor and date of last monitoring event:  | Name: Click or tap here to enter text.Date: Click or tap to enter a date.  |

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| **Staff Signature Log** | **Yes** | **No** |
| 1 | Is there a staff signature log? *If no, skip to* ***Investigational Drugs*** |[ ] [ ]
| 2 | Is the staff signature log up to date? |[ ] [ ]
| 3 | Does the staff signature log include information regarding delegation of responsibility? |[ ] [ ]

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| **Investigational Drugs, Devices, Biologics** | **Yes** | **No** |
| 1 | Is this an investigational drug or device study? *If no, skip to* ***Laboratory Results*** |[ ] [ ]
| 2 | Below please list the most current version number/date of the following documents, as applicable: |
|  | **Document**  | **Version Number/Date** |
|  | Investigator Brochure | Click or tap here to enter text. |
|  | Labelling | Click or tap here to enter text. |
|  | Device Manual  | Click or tap here to enter text. |
|  | Package Insert | Click or tap here to enter text. |
|  | Product Information  | Click or tap here to enter text. |

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| **Laboratory Results** | **Yes** | **No** |
| 1 | Are lab tests required? *If no, skip to* ***Data******Safety Monitoring*** |[ ] [ ]
| 2 | Is a copy of normal lab values saved either in a study file or in Kuali? |[ ] [ ]
| 3 | Is lab certification in file (e.g. CLIA)? *This should include the current version and all superseded copies. If this is an IND study, documentation for all labs listed on the FDA 1572 must be on file*.  |[ ] [ ]
| 4 | Is a current CV for the lab director, dated within the last two years and signed, saved in a study binder (paper, electronic, or both)?  |[ ] [ ]

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| **Data Safety Monitoring**  | **Yes** | **No** |
| 1 | Is there a data safety monitoring plan (DSMP) or data oversight panel for this study? *If no, skip to* ***IRB Documentation*** |[ ] [ ]
| 2 | Does the plan involve a data safety monitoring board (DSMB)? *If no, skip to* ***IRB Documentation*** |[ ] [ ]
| 3 | Has the DSMB met in accordance with the IRB-approved protocol?  |[ ] [ ]
| 4 | Are appropriate DSMB reports or indications of DSMB reviews and recommendations saved in a study binder (paper, electronic, or both)?  |[ ] [ ]
| 5 | Please list the number of DSMB reviews and dates below: (*add lines as needed*) |
|  | **DSMB Review**  | **Dates** |
|  | Click or tap here to enter text. | Click or tap here to enter text. |
|  | Click or tap here to enter text. | Click or tap here to enter text. |
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| Please describe any areas of concern identified above, action(s) to take or taken, or other comments:  |
| Click or tap here to enter text. |

**IRB DOCUMENTATION**

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| **General IRB Correspondence** | **Yes** | **No** |
| 1 | Is all correspondence with the IRB saved in a study binder (paper, electronic, or both)? *This should include applications, responses, emails, and approvals* |[ ] [ ]

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| **Initial Review** | **Yes** | **No** |
| 1 | Is the initial IRB approval letter saved in a study binder (paper, electronic, or both)?  |[ ] [ ]

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| **Continuing Reviews** | **Yes** | **No** |
| 1 | Has there been a lapsed between expiration date and continuing review approval date? *If no, skip to* ***Amendments*** |[ ] [ ]
| 2 | Were any subjects enrolled during the lapse? *If no, skip to* ***#3*** |[ ] [ ]
| 3 | Were any study procedures conducted during the lapse? *If no, skip to* ***Amendments*** |[ ] [ ]
| 4 | Please explain what procedures were conducted: Click or tap here to enter text. |
| 5 | Were the procedures justified in writing in order to ensure safety/well-being of the participant, and approved by the LSUHSC-NO IRB?  |[ ] [ ]

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| **Amendments** | **Yes** | **No** |
| 1 | Were amendments submitted and approved by the IRB prior to implementation of the changes? *If no, skip to* ***Subject Recruitment*** |[ ] [ ]
| 2 | Were there any changes that were not IRB-approved? *If no, skip to* ***#4*** |[ ] [ ]
| 3 | Describe the changes and why they were not approved by the IRB: Click or tap here to enter text. |
| 4 | How many amendments have been submitted to the IRB? | # |
| 5 | Please summarize the amendment history below: (*add lines as needed*) |
|  | **Date Submitted** | **Date Approved** | **Revised Documents Submitted** | **Approval Saved** |
|  |  |  |  | **Yes** | **No** |
|  | Click or tap to enter a date. | Click or tap to enter a date. | Click or tap here to enter text. |[ ] [ ]
|  | Click or tap to enter a date. | Click or tap to enter a date. | Click or tap here to enter text. |[ ] [ ]
|  | Click or tap to enter a date. | Click or tap to enter a date. | Click or tap here to enter text. |[ ] [ ]

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| Please describe any areas of concern identified above, action(s) to take or taken, or other comments:  |
| Click or tap here to enter text. |

**SUBJECT RECRUITMENT PROCEDURES**

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| **Recruitment Methods** |
| 1 | How are potential subjects identified? (*check all methods that apply*) | [ ]  Clinical Practice [ ]  Investigators[ ]  Database[ ]  Medical Record Review [ ]  Other: Click or tap here to enter text.[ ]  Not Applicable (*Skip to* ***Subject***  ***Selection***) |
|  | **Yes** | **No** |
| 2 | Are the recruitment methods identified above stated in the currently approved protocol/application?  |[ ] [ ]
| 3 | Is initial contact made in compliance with the IRB-approved activities for the study?  |[ ] [ ]
| 4 | Is this community-based research? *If no, skip to* ***Recruitment Materials***  |[ ] [ ]
| 5 | Have there been community forums to explain the study? *If no, skip to* ***Recruitment Materials*** |[ ] [ ]
| 6 | How many community forums have been held? |[ ] [ ]
| 7 | Are community members/leaders involved in your study?  |[ ] [ ]

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| **Recruitment Materials** |
| 1 | What recruitment materials have been used? (*check all materials that apply*) | [ ]  Print Advertisements[ ]  Social Media Advertisements[ ]  Television or Radio Advertisements[ ]  Flyers[ ]  Emails[ ]  Letters[ ]  Telephone Scripts[ ]  Pre-screening Forms [ ]  Other: Click or tap here to enter text.[ ]  None *(Skip to* ***Subject Selection****)* |
|  | **Yes** | **No** |
| 2 | Have all recruitment materials identified above been approved by the IRB?  |[ ] [ ]
| 3 | Are all approved recruitment materials saved in a study binder (paper, electronic, or both)??  |[ ] [ ]
| 4 | Have all changes to recruitment materials been submitted to the IRB for review?  |[ ] [ ]
| 5 | Is recruitment at the expected level for this study? |[ ] [ ]
| 6 | Estimated closure date for enrollment: Click or tap to enter a date. |

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| Please describe any areas of concern identified above, action(s) to take or taken, and other comments:  |
| Click or tap here to enter text. |

**SUBJECT SELECTION CRITERIA**

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| **Subject Selection** |
| 1 | Number of Enrolled Participants to Date: *“Enrolled” refers to a person who has signed an informed consent document, even if they were withdrawn later on.* | # |
|  | **Yes** | **No** |
| 2 | Is enrollment at the expected level for this study? *If yes, skip to* ***#3*** |[ ] [ ]
| 3 | If enrollment is low relative to the goal, is there a plan to meet the goal? |[ ] [ ]
| 4 | Is there an eligibility checklist containing inclusion/exclusion criteria?  |[ ] [ ]
| 5 | Does each participant’s file indicate whether the participant was properly included or excluded?  |[ ] [ ]
| 6 | Please select 3 random participant files and indicate whether the participant was included/excluded appropriately:  |
|  | Participant #1: Click or tap here to enter text. |[ ] [ ]
|  | Participant #2: Click or tap here to enter text. |[ ] [ ]
|  | Participant #3: Click or tap here to enter text. |[ ] [ ]
| 7 | Were any participants enrolled who did not meet the eligibility criteria? *If no, skip to* ***#9*** |[ ] [ ]
| 8 | Were these reported as protocol deviations or appropriately documented on the Event Tracking Log?  |[ ] [ ]
| 9 | Do the subjects enrolled reflect equitability, allowing for distribution of the risk among persons (race, gender, etc.) who have a potential for future benefit?  |[ ] [ ]
| 10 | Does the current distribution of subjects by race, gender, etc., meet expectations as outlines within the protocol or IRB application?  |[ ] [ ]
| 11 | Are recruitment, enrollment, interventions, or any other study activities ongoing? |[ ] [ ]
| 12 | Number of subjects excluded:  | # |
| 13 | Number of subjects who voluntarily withdrew: | # |

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| **Compensation** | **Yes** | **No** |
| 1 | Is compensation provided? *If no, skip to* ***Informed Consent*** |[ ] [ ]
| 2 | Is it consistent with the protocol? |[ ] [ ]
| 3 | Is the amount and type of compensation still appropriate?  |[ ] [ ]

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| Please describe any areas of concern identified above, action(s) to take or taken, or other comments:  |
| Click or tap here to enter text. |

**INFORMED CONSENT PROCESS**

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| **Informed Consent** |
| 1 | Below please list all consent/assent and HIPAA documents by the date approved by the IRB (*add lines as needed*) |
|  | **Version ID** | **IRB Approval Date** |
|  | Click or tap here to enter text. | Click or tap to enter a date. |
|  | Click or tap here to enter text. | Click or tap to enter a date. |
|  | Click or tap here to enter text. | Click or tap to enter a date. |
|  | **Yes** | **No** |
| 2 | Are all prior IRB-approved versions of the consent materials being retained? |[ ] [ ]
| 3 | Does the location where consenting take place allow for participants to preserve their privacy? |[ ] [ ]
| 4 | Are subjects given the time to review the consent materials, discuss it with the Investigator or person consenting, and have their questions answered? |[ ] [ ]
| 5 | Does the study personnel responsible for consenting review the documents for completion to ensure all applicable information has been filled in?  |[ ] [ ]
| 6 | Are appropriate procedures in place to evaluate potential participants to ensure they have the capacity to consent for themselves?  |[ ] [ ]
| 7 | Is a legally authorized representative (LAR) used in the informed consent process? *If no, skip to* ***#11*** |[ ] [ ]
| 8 | Were participants re-consented once they regained the ability to give their own consent? *If yes, skip to* ***#11*** |[ ] [ ]
| 9 | If not, please provide an explanation: Click or tap here to enter text. |
| 10 | Are subjects given a copy of the consent form to take home?  |[ ] [ ]
| 11 | Is the consent process documented in the study file?  |[ ] [ ]
| 12 | Is consenting an ongoing process? *If no, skip to* ***#15*** |[ ] [ ]
| 13 | When after initial consent is the participant consented again? Click or tap here to enter text. |
| 14 | How often is the participant re-consented? Click or tap here to enter text. |
| 15 | Is documentation maintained when a participant revokes their consent?  |[ ] [ ]
| 16 | Are consent materials provided in languages other than English?  |[ ] [ ]
| 17 | Will the study personnel be re-contacting participants after study completion for any reason? |[ ] [ ]
| 18 | Is information about re-contacting listed in the consent form? |[ ] [ ]

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| **HIPAA/Notice of Privacy Practice**  | **Yes** | **No** |
| 1 | Is each participant completing an HIPAA authorization? *If no, skip to* ***Educational Materials*** |[ ] [ ]
| 2 | Was a waiver of HIPAA authorization granted by the IRB? |[ ] [ ]
| 3 | Is a copy of the Notice of Privacy Practices provided to participants? *If no, skip to* ***#5*** |[ ] [ ]
| 4 | Is an Acknowledgement of the Notice of Privacy Practices being signed by all participants? |[ ] [ ]
| 5 | Is documentation maintained when a participant revokes authorization?  |[ ] [ ]

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| **Educational Materials**  | **Yes** | **No** |
| 1 | Do you provide educational materials to the participant? *If no, skip to* ***File Review Exercise*** |[ ] [ ]
| 2 | Please attach a copy of the educational materials when you submit this form. |

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| **File Review Exercise** |
| Please use the participant files chosen for the inclusion/exclusion check to complete the following questions pertaining to the informed consent process.  |
| Participant ID | IRB approval stamp date | Copies of all signed documents in the file?  | Consent/assent signed/dated? | HIPAA Authorization signed/dated? | Documentation of Acknowledgement of Notice of Privacy Practices? | Documentation that the participant received a copy of the signed/dated consent? |
| ID Only | Date | Yes | No | Yes | No | Yes | No | Yes | No | Yes | No |
| # | Click or tap to enter a date. |[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]
| # | Click or tap to enter a date. |[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]
| # | Click or tap to enter a date. |[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]

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| Please describe any areas of concern identified above, action(s) to take or taken, or other comments:  |
| Click or tap here to enter text. |

**RISK/BENEFIT**

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| **Risk/Benefit Overview**  | **Yes** | **No** |
| 1 | Have the risks/benefits changed since the last submission of an application to the IRB? *If no, skip to* ***#3*** |[ ] [ ]
| 2 | Please elaborate on the changes to the risks/benefits: Click or tap here to enter text. |
| 3 | Is there any new relevant information that may impact the risks or benefits of the research? *If no, skip to* ***Unanticipated Problems*** |[ ] [ ]
| 4 | Has the information been submitted to the IRB?  |[ ] [ ]

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| Please describe any areas of concern identified above, action(s) to take or taken, or other comments:  |
| Click or tap here to enter text. |

**UNANTICIPATED PROBLEMS & UNEXPECTED ADVERSE EVENTS**

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| **Unanticipated Problems Overview**  | **Yes** | **No** |
| 1 | Have there been any Unanticipated Problems or local Serious Adverse Events (SAEs) reported for this study?  |[ ] [ ]
| 2 | Have any unanticipated problems or local SAEs been identified during this review? *If no, skip to* ***Participant Complaints*** |[ ] [ ]
| 3 | Have all Unanticipated Problems or local SAEs been reported according to IRB guidelines?  |[ ] [ ]
| 4 | Have all unanticipated problems been reported to the sponsor and/or FDA, as applicable? |[ ] [ ]
| 5 | Number of Unanticipated Problems and local SAEs reported:  | # |
| 6 | Number of unanticipated problems and local SAEs pending review:  | # |
| 7 | Please describe the problem(s) and the action(s) taken to resolve them below: (*add lines as needed*) |
|  | **Problems** | **Resolutions** |
|  | Click or tap here to enter text. | Click or tap here to enter text. |
|  | Click or tap here to enter text. | Click or tap here to enter text. |
|  | Click or tap here to enter text. | Click or tap here to enter text. |

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| **Participant Complaints**  | Yes | No |
| 1 | Have there been any complaints from participants? *If no, skip to* ***Protocol Deviations*** |[ ] [ ]
| 2 | Please describe the complaint(s) and the action(s) taken to resolve them below: (*add lines as needed*) |
|  | **Complaints** | **Resolutions** |
|  | Click or tap here to enter text. | Click or tap here to enter text. |
|  | Click or tap here to enter text. | Click or tap here to enter text. |
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| Please describe any areas of concern identified above, action(s) to take or taken, or other comments:  |
| Click or tap here to enter text. |

**PROTOCOL DEVIATIONS**

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| Deviations Overview  | **Yes** |  **No** |
| 1 | Have there been any protocol deviations reported? *If no, skip to* ***Drug/Device Dispensing Accountability*** |[ ] [ ]
| 2 | Have all protocol deviations been reported to the IRB or documented on the Reportable New Information (RNI) Event Tracking Log? |[ ] [ ]
| 3 | Have all protocol deviations been reported to the sponsor, as appropriate? |[ ] [ ]
| 4 | How many protocol deviations have been documented on the RNI Event Tracking Log, if any? | # |
| 5 | Please describe the deviations(s) and the step(s) taken to prevent further deviations below: (*add lines as needed*) |
|  | **Deviations** | **Steps Taken** | **Reported to IRB?** |
|  |  |  | **Yes** | **No** |
|  | Click or tap here to enter text. | Click or tap here to enter text. |[ ] [ ]
|  | Click or tap here to enter text. | Click or tap here to enter text. |[ ] [ ]
|  | Click or tap here to enter text. | Click or tap here to enter text. |[ ] [ ]

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| Please describe any areas of concern identified above, action(s) to take or taken, or other comments:  |
| Click or tap here to enter text. |

**DRUG/DEVICE DISPENSING ACCOUNTABILITY**

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| **Drug/Device Accountability Overview** | **Yes** | **No** |
| 1 | Is this a drug or device study? *If not, skip to* ***Record Keeping and Data Security*** |[ ] [ ]
| 2 | Who is authorized to dispense and/or administer the drug/device? (*select all that apply*) | [ ]  Investigator[ ]  Research Nurse[ ]  Coordinator[ ]  Other: Click or tap here to enter text. |
|  | **Yes** | **No** |
| 3 | Have those authorized to dispense and/or administer received the appropriate training?  |[ ] [ ]
| 4 | Is the drug/device stored in a secure location? |[ ] [ ]
| 5 | Please state where the drug/device is stored: Click or tap here to enter text. |
| 6 | Are all refrigerated storage units locked? |[ ] [ ]
| 7 | Are temperature/humidity logs maintained for all investigational products stored outside the Investigational Drug Pharmacy? |[ ] [ ]
| 8 | Who is responsible for instructing subjects on how to use the medication or device?  | [ ]  Investigator[ ]  Research Nurse[ ]  Coordinator[ ]  Other: Click or tap here to enter text. |
| 9 | How much time is spent on subject instruction? Click or tap here to enter text. |
| 10 | Is there documentation of drug/device use for each participant?  |[ ] [ ]
| 11 | Is a dispensing and accountability log being maintained? |[ ] [ ]
| 12 | Is there documentation for the return or destruction of the drug/device? |[ ] [ ]
| 13 | Have there been any drug/device errors? *If no, skip to* ***#15*** |[ ] [ ]
| 14 | Have all drug/device errors been properly reported to the sponsor and the IRB? |[ ] [ ]
| 15 | Have any temperature excursions occurred with the investigational product? *If no, skip to* ***Shipping*** |[ ] [ ]
| 16 | Were the temperature excursions reported to the IRB and sponsor?  |[ ] [ ]

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| --- | --- | --- |
| **Shipping** | **Yes** | **No** |
| 1 | Are copies of shipping receipts kept? |[ ] [ ]
| 2 | Who is responsible for shipping/receiving? | [ ]  Investigator[ ]  Investigational Drug Pharmacy[ ]  Study Staff[ ]  Other: Click or tap here to enter text. |

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| Please describe any areas of concern identified above, action(s) to take or taken, or other comments:  |
| Click or tap here to enter text. |

**RECORD KEEPING & DATA SECURITY**

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| **Record Keeping**  | **Yes** | **No** |
| 1 | Is there a written disaster recovery and/or project continuity plan for the study?  |[ ] [ ]
| 2 | Is there a binder/folder for all regulatory documents?  |[ ] [ ]
| 3 | Is there a binder/folder/section for IRB correspondence?  |[ ] [ ]
| 4 | Is there a study file for each subject? *If no, skip to* ***Data Security***  |[ ] [ ]
| 5 | Are the study files stored separately from consent materials?  |[ ] [ ]
| 6 | Are the study files for each subject coded by a unique number/letter combination (required by 45 CFR § 164.514), with the code stored in a secure location?  |[ ] [ ]

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| **Data Security** | **Yes** | **No** |
| 1 | Have there been any breaches in privacy or confidentiality that met the definition of an unanticipated problem? *If no, skip to* ***#3*** |[ ] [ ]
| 2 | Please describe the breach(es) and the action(s) taken to resolve the issue: (*add lines as needed*) |
|  | **Breaches** | **Resolutions** |
|  | Click or tap here to enter text. | Click or tap here to enter text. |
|  | Click or tap here to enter text. | Click or tap here to enter text. |
|  | Click or tap here to enter text. | Click or tap here to enter text. |
|  | **Yes** | **No** |
| 3 | Are any Personal Health Information data kept in electronic files? |[ ] [ ]
| 4 | What type of electronic file is being used? | [ ]  REDCAP[ ]  Excel[ ]  Other: Click or tap here to enter text. |
| 5 | Please provide a current copy of the data collection sheet. |  |  |
| 6 | Are you storing data on a computer and/or portable storage device? *If no, skip to* ***#9*** |[ ] [ ]
| 7 | Are the devices password-protected and/or encrypted? *If no, skip to* ***#9*** |[ ] [ ]
| 8 | Please indicate what protection is used:  | [ ]  Passwords[ ]  Encryption[ ]  Other: Click or tap here to enter text. |
| 9 | Are data in storage de-identified according to HIPAA regulations? |[ ] [ ]
| 10 | Where is data being stored? | [ ]  University Secure Server[ ]  Portable Device [ ]  Other: Click or tap here to enter text. |
| 11 | Is the data stored in a secure location? |[ ] [ ]
| 12 | Does each person with access to the data have their own unique password? |[ ] [ ]
| 13 | Do you use an electronic survey or data gathering tool?  |[ ] [ ]
| 14 | Please describe the system/tool being used: Click or tap here to enter text. |
| 15 | Please describe how privacy and confidentiality is being protected: Click or tap here to enter text. |

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| Please describe any areas of concern identified above, action(s) to take or taken, or other comments:  |
| Click or tap here to enter text. |