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| **Study Title:** | |
| **Investigator:** | **IRB#:** |
| **Completed By:** | **Date Completed:** |

**Instructions**

This Self-Monitoring Tool is designed for use as part of the overall Data Safety Monitoring Plan (DSMP) to assess compliance with IRB policies and procedures and federal regulations and guidance governing research with human subjects, on a per-study basis. This form can be modified to include review of the specific human subject protection and data integrity risks of the trial. Site monitoring should be completed regularly once subjects have been enrolled.

As you complete this form, please consider the IRB’s reporting requirements for adverse events, protocol deviations and noncompliance. Event Examples and reporting requirements are shown here:  [Event Reporting](https://orrp.osu.edu/irb/investigator-guidance/event/) [external link]

**Contact ORRP with questions 614-688-2208.**

IRB-approved subject sample size: \_\_\_\_\_

Number of subjects who signed consent (enrolled) to date: \_\_\_\_\_\_

Number of withdrawals: \_\_\_

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| **Section A: Regulatory** | | | | |
| **Regulatory Responsibilities** | | **Yes** | **No** | **NA** |
| **1** | Are all staff working on the study listed on the IRB submission? |  |  |  |
| **2** | Is CITI Human Subject’s certification and protocol training current for all study team members? (no term lapses) |  |  |  |
| **3** | If NIH sponsored, is Good Clinical Practices documented and current for all study team members? (no term lapses) |  |  |  |
| **4** | Has the study maintained continuous active IRB approval? |  |  |  |
|  | If No, any activities that occurred during the lapse reported to the IRB? |  |  |  |
| **5** | If subjects withdrew, were these withdrawals reported to the IRB at continuing review? |  |  |  |
| **6** | Have all study data collected in the past 30 days been entered into the study database as required by the protocol, contract, or standard operating procedure? |  |  |  |
| **7** | Is the IRB approved plan for storage & dispensation of the test article being followed? |  |  |  |
| **8** | If re-consent of subjects was required by IRB or sponsor, were all subjects appropriately re-consented? |  |  |  |
| **9** | Is the IRB approved DSMP being followed? |  |  |  |
| **10** | Is the data protection plan being followed, including use of encrypted devices? |  |  |  |

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| **Section B: Reporting** | | | | |
| **Reporting Responsibilities** | | **Yes** | **No** | **NA** |
| **1** | Are there reporting requirements (e.g. SAEs or deviations) to the sponsor or funding source? |  |  |  |
|  | If yes, were reports submitted as required? |  |  |  |
| **2** | Have all protocol deviations/protocol non-compliance and/or non-compliance with IRB Policies and Procedures, federal regulations, or funding requirements been reported to the IRB per their requirements? |  |  |  |
| **3** | Have all events that require prompt reporting been reported to the IRB? |  |  |  |
| **4** | Have all events that require periodic reporting been reported at the time of continuing review? |  |  |  |

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| **Section C: Regulatory Documentation Review** | | |
| **Document** | **Yes, No or N/A** | **Comments:** Note if an item is maintained in a location other than the regulatory binder and confirm documentation of the location in the regulatory binder |
| **Investigator Brochures, package inserts, or device manuals** with signature pages, if applicable |  | Current version/date­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date submitted to IRB \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Protocol/protocol amendment** with signature page, if applicable |  | Current version/date­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date approved by IRB \_\_\_\_\_\_\_\_\_\_\_\_\_  Current study approval period: \_\_\_\_\_\_\_\_\_\_\_ |
| **ICF, HIPAA authorization form** and, if applicable, revocation letter |  | Current ICF version/date­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date approved by IRB \_\_\_\_\_\_\_\_\_\_\_\_\_  Current authorization version/date­­­­\_\_\_\_\_\_\_  Date approved by IRB \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Institutional Review Board reviews**  Documentation of IRB approval: protocol and amendments, continuing review, ICFs, trial information for subjects, advertisements, and other |  | Current study approval period: \_\_\_\_\_\_\_\_\_\_\_ |
| **Investigator agreement or Form FDA 1572** signed by site PI with current listing of all sub-investigators & facilities |  |  |
| **CV, licenses** and/or other relevant documents evidencing qualifications of investigators and sub investigators |  |  |
| **FDA** **Financial**  **Disclosure Certification Forms** (FDF) completed by each investigator |  |  |
| **Delegation of Authority (DOA) Log**: may include a site signature log |  |  |
| **Records of Study Specific training** including updates for each individual listed on DOA Log |  |  |
| **Reportable Events: SAEs, UPs or non-compliance** includingsafety reports, internal & external with documentation of review |  | Required reports to IRB, date:\_\_\_\_\_\_ |
| **Data and Safety Monitoring Committee Reports** |  | Required reports to IRB, date:\_\_\_\_\_\_ |
| **Site Monitoring Log & Reports** |  | Site monitoring completed, date:\_\_\_\_\_\_\_\_  Required reports to CTAC, date:\_\_\_\_\_\_ |
| **Investigational product IP** documentation of disposition (dates, quantity, use by subjects, and return). Note if drug is managed by IDS. |  |  |
| **Screening and enrollment logs** |  |  |
| **Laboratory**  Certifications/accreditations; normal lab values |  |  |
| **Ancillary Committee Approvals, if applicable** |  |  |
| **Miscellaneous** |  |  |

Does the PI hold an IND or IDE for this study?  Yes  No

If Yes, continue below to the Sponsor-Investigator Regulatory Documentation Review. If No, skip to section D.

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| **Document** | **Yes, No or N/A** | **Comments:** Note if an item is maintained in a location other than the regulatory binder and confirm documentation of the location in the regulatory binder |
| **FDA submissions with accompanying 1571**  Original application**;** FDA correspondence; amendments; IND Safety Reports (MedWatch); annual reports |  | IND Anniversary Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Current IND Annual Report ­­­\_\_\_\_\_\_\_\_\_\_\_\_  Date submitted to FDA\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date submitted to IRB\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Reportable Events: SAEs, UPs or non-compliance** includingSafety Reports, internal & external with documentation of review |  | Required Reports to IRB, date:\_\_\_\_\_\_ |
| **clinicaltrials.gov information updated within past 6 months** |  | Updated:**\_\_\_\_\_\_\_\_\_\_\_\_\_** |
| **Investigational product (IP)** documentation  copy of label(s) attached to IP; shipping records for IP (note if drug managed by IDS) |  |  |

Is this a multisite study where the OSU PI holds the IND or IDE?  Yes  No

If Yes, continue below to the Multisite documentation review. If No, skip to section D.

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| **Document** | **Yes, No or N/A** | **Comments:** Note if an item is maintained in a location other than the regulatory binder and confirm documentation of the location in the regulatory binder |
| **Site contact information sheet** |  |  |
| **Signature pages:**  Protocol/protocol amendment signature page  Investigator brochure/package insert/device manual signature pages  Site signature log (to document entries on source documents) |  |  |
| **Agreements:** Signed site agreement& any other agreement between involved parties |  |  |
| **IRB** local IRB Composition; documentation of IRB approval (protocol and amendments, ICFs) |  | Current study approval period: \_\_\_\_\_  Current protocol version/date­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_  Date approved by IRB \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **ICF, HIPAA authorization** and, if applicable, revocation letter |  | Current ICF version/date­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date approved by IRB \_\_\_\_\_\_\_\_\_\_\_\_\_  Current authorization version/date­­­­\_\_\_\_\_\_\_  Date approved by IRB \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Form FDA 1572 or Investigator Agreement** signed by site PI listing all sub-investigators |  |  |
| **CV and license of site PI** |  |  |
| **FDA** **Financial Disclosure Certification Forms** (FDF) completed by each investigator listed on Form 1572 or Investigator agreement |  |  |
| **Records of sponsor provided training** |  |  |
| **Safety reports**, with documentation of review & assessment by the IND/IDE sponsor & communication of safety information to participating investigators |  | Required reports to  IRB, date:\_\_\_\_\_\_\_\_\_  FDA, date:\_\_\_\_\_\_\_\_\_  Participating investigators, date:\_\_\_\_\_\_\_\_ |
| **Laboratory**  Certifications/accreditations; normal lab values |  |  |
| **Investigational Product (IP)**  Copy of labels attached to IP; shipping records for IP (note if managed by Emory IDS) |  |  |
| **Site monitoring reports & follow-up documentation** |  | Site monitoring completed, date:\_\_\_\_\_\_\_\_  Required reports to CTAC, date:\_\_\_\_\_\_ |
| **Correspondence to individual site** (including trial updates, updated product or safety information, teleconference minutes) |  |  |
| **Miscellaneous** |  |  |

In section D please select 3 or more subjects to review the following.

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| **Section D: Subject Case History Review** | | | | |
| **Subject 1 ID#:** | | **Yes** | **No** | **NA** |
| **1** | Is there an original copy of informed consent form (ICF) and HIPAA authorization on file? |  |  |  |
| **2** | Was the person who obtained informed consent authorized by the IRB to obtain consent for this study? |  |  |  |
| **3** | Did the subject sign and date the ICF prior to the research procedures? |  |  |  |
| **4** | Is there documentation of the consent process in the research record which includes that the subject received a copy of the ICF? |  |  |  |
| **5** | Were the correct versions of the ICF and HIPAA used? |  |  |  |
| **6** | Is each document properly completed with initials/signatures? |  |  |  |
|  | If No explain: |  |  |  |
| **7** | Did the subject meet eligibility criteria? |  |  |  |
| **8** | Is documentation of eligibility complete and in the record? |  |  |  |
| **9** | Were subject visits conducted in the timeframe required by the protocol? |  |  |  |
| **10** | Were all tests/procedures performed and documented according to the protocol? |  |  |  |
| **11** | Did this subject experience any adverse events? |  |  |  |
|  | If yes is there documentation of timely review and assessment? |  |  |  |
| **12** | Has the data for this subject been entered into the study database within the required timeframe of the protocol or by the sponsor, but no later than 30 days? |  |  |  |

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| **Subject 2 ID#:** | | **Yes** | **No** | **NA** |
| **1** | Is there an original copy of informed consent form (ICF) and HIPAA authorization on file? |  |  |  |
| **2** | Was the person who obtained informed consent authorized by the IRB to obtain consent for this study? |  |  |  |
| **3** | Did the subject sign and date the ICF prior to the research procedures? |  |  |  |
| **4** | Is there documentation of the consent process in the research record which includes that the subject received a copy of the ICF? |  |  |  |
| **5** | Were the correct versions of the ICF and HIPAA used? |  |  |  |
| **6** | Is each document properly completed with initials/signatures? |  |  |  |
|  | If No, explain: |  |  |  |
| **7** | Did the subject meet eligibility criteria? |  |  |  |
| **8** | Is documentation of eligibility complete and in the record? |  |  |  |
| **9** | Were subject visits conducted in the timeframe required by the protocol? |  |  |  |
| **10** | Were all tests/procedures performed and documented according to the protocol? |  |  |  |
| **11** | Did this subject experience any adverse events? |  |  |  |
|  | If yes is there documentation of timely review and assessment? |  |  |  |
| **12** | Has the data for this subject been entered into the study database within the required timeframe of the protocol or by the sponsor, but no later than 30 days? |  |  |  |
|  |  |  |  |  |
| **Subject 3 ID#:** | | **Yes** | **No** | **NA** |
| **1** | Is there an original copy of informed consent form (ICF) and HIPAA authorization on file? |  |  |  |
| **2** | Was the person who obtained informed consent authorized by the IRB to obtain consent for this study? |  |  |  |
| **3** | Did the subject sign and date the ICF prior to the research procedures? |  |  |  |
| **4** | Is there documentation of the consent process in the research record which includes that the subject received a copy of the ICF? |  |  |  |
| **5** | Were the correct versions of the ICF and HIPAA used? |  |  |  |
| **6** | Is each document properly completed with initials/signatures? |  |  |  |
|  | If No explain: |  |  |  |
| **7** | Did the subject meet eligibility criteria? |  |  |  |
| **8** | Is documentation of eligibility complete and in the record? |  |  |  |
| **9** | Were subject visits conducted in the timeframe required by the protocol? |  |  |  |
| **10** | Were all tests/procedures performed and documented according to the protocol? |  |  |  |
| **11** | Did this subject experience any adverse events? |  |  |  |
|  | If yes is there documentation of timely review and assessment? |  |  |  |
| **12** | Has the data for this subject been entered into the study database within the required timeframe of the protocol or by the sponsor, but no later than 30 days? |  |  |  |

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| **Section E: Regulatory** |

**Action Required**

*For any questions answered No above, determine if there are reporting requirements.*

Do any findings require action?  Yes  No  N/A

If yes, specify?

* + Report to IRB
  + Report to sponsor
  + Report to funding source
  + Other action

|  |
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| **Section F: Corrective and Preventive Action Plan** |

*For any questions answered No, also determine if a Corrective and Preventive Action (CAPA) Plan is required. If required, please describe the CAPA including the corresponding item identifier, e.g., A-4 CITI certification, as a header and implementation/completion dates.*

**Item Identifier:**

Problem:

Root Cause:

Corrective Action:

Preventive Action:

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Signature and date of study staff member completing this form

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature and date of Investigator reviewing this form

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Signature and date of Clinical Research Manager reviewing this form, if applicable