**Study Source Data Plan**

**The purpose of this plan is to document the location of specific study data first recorded at this site for use by study monitors and investigators.**

**Instructions to investigators/site research team members:** *[Insert sponsor- or site-specific instructions about the purpose of the table, how to fill it out and what categories of study-specific documents must appear on the list (e.g., the categories of data that will be entered from the source documents into the electronic data capture system and will require verification at time of monitoring or audit).]*

*Examples of Source Data Locations: Patient electronic medical record system; subject research binder; direct electronic capture via sponsor/vendor tablet (or other eSource capture system); central lab web site; pharmacy drug accountability log binder; storage temperature logbooks; investigator site file.*

| **Sponsor:** | **Protocol Number:** |
| --- | --- |
| **Principal Investigator Name & #:** |  |
| **Site Address:** |
| **Data Type or Item** | **Source Data/Document Location*****Insert guidance on who will fill out this column and who will assist – e.g., Investigators will complete with site staff and monitor during site initiation visit.*** |
| **Informed Consent** |
| Written informed consent/assent & supplemental consent form |  |
| Informed consent progress note |  |
| Informed consent SOP/institutional guidelines |  |
| **Subject & Study Basic Information** |
| Medical history |  |
| Demography (including date of birth, race, ethnicity, height, weight, sex) |  |
| Eligibility criteria |  |
| Subject randomization information (including treatment assignment & subject visit date) |  |
| **Assessments** |
| Physical examination |  |
| Vital signs |  |
| Questionnaires |  |
| Patientreported outcomes *(List specific names of outcomes)* |  |
| Lab results *(List specific lab tests)* |  |
| Diagnostic assessments *(List specific imaging or diagnostic procedures or assessments)* |  |
| **Medications and Investigational Product (IP)** |
| Prior medications |  |
| Concomitant medications |  |
| Investigational product storage conditions, temperature excursion information & overall accountability |  |
| Patient-level dispensing & return, compliance, accountability, dosing, preparation & administration |  |
| **Subject Safety** |
| SAE |  |
| AE |  |
| Pregnancy |  |
| Reasons for study withdrawal/ discontinuation/completion, IP interruption |  |
| Study endpoint |  |
| Events of special interest |  |
| Study-specific subject training |  |
| **Essential Documents** |
| Essential documents (e.g., 1572, CVs) |  |

**Investigator’s Agreement**

*[Insert statements for the investigator to sign in acknowledgement. For example, a statement to understand the purpose of source documents and this tool. A statement of the investigator and site research team to demonstrate that responsibility follows source document maintenance recommendations (update table as needed) and provides appropriate source document access for monitors and auditors.]*

|  |  |
| --- | --- |
| Principal Investigator’s Signature: | Date: |
| Principal Investigator’s Name:(please print) |  |

*[Insert instructions on where to file this document. For example, in what tab of the investigator site file it should be placed.]*