| ***Source Data*** | ***Provide Original Source Document (SD) Details:***  Provide details on the format/type of SD (e.g., medical chart, discharge summary, paper medical record, EMR) | ***Provide Original Source Document Location(s) at Site*:**  Specify where the Source may be found (e.g., specify which file; in whose office, which ward; Medical Records Department, EMR system at Imaging department, Lab, etc.) | ***Comments/***  ***Additional Information***  E.g., indicate when certified copies will be provided to Monitor or how Monitor will access SDs in case read-only access to EMR system is not granted (i.e., over the shoulder monitoring - reviewing EMR while Investigator team member navigates the system); any relevant information about the SDs at site, as applicable |
| --- | --- | --- | --- |
| *Subject ICF* |  |  |  |
| *Subject Informed Consent Process* |  |  |  |
| *Withdrawal of Consent/ Withdrawal of Consent Discussion* |  |  |  |
| *Subject Demographics* |  |  | 上述内容由CRA填写，是关于原始数据的存放位置 |
| *Subject Screening / Randomization Number* |  |  |  |
| *Note on Subject Study Participation* |  |  |  |
| *Meeting inclusion /exclusion criteria (Investigator’s assessment of eligibility)* |  |  |  |
| *Medical History (including prior medication)* |  |  |  |
| *Initial Diagnosis* |  |  |  |
| *Hospitalization Details / Visit Dates* |  |  |  |
| *Vital Signs* |  |  |  |
| *Physical Exam / Baseline conditions* |  |  |  |
| *Investigational Product (IP) Administration/Dispensation / IP Compliance* |  |  |  |
| *Concomitant Medication* |  |  |  |
| *Adverse Events / Serious Adverse Events* |  |  |  |
| *Laboratory Results* |  |  |  |
| *Subject contacts with site (during the course of the study)* |  |  |  |
| *Weight, Height, BMI / BSA\** |  |  |  |
| *ECG Recordings\** |  |  |  |
| *CT/MRI and other imaging Scan results, including images\** |  |  |  |
| *X-Ray results, including images\** |  |  |  |
| *Pathology / Histology\** |  |  |  |
| *Subject / Caregiver Reported Outcomes (e.g. SF36, EQ5D, etc.)\** |  |  |  |
| *Rating scales / clinician assessments (e.g. C-SSRS, EDSS, etc.)\** |  |  |  |
| *Subject Diaries\** |  |  |  |
| *Other (specify):* |  |  |  |

My signature confirms the following:

* The source data location information on this log is complete and accurate and has been communicated to all site staff members

启动会当天

* I agree to maintain the information on this log accurate

PI英文姓名

PI英文签字

* I agree to grant Monitor direct access to all source documents from all systems as indicated above, including any updates to the source documents.

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| **Investigator’s Name:** | **Investigator’s Signature:** | **Date Signed:** |

**2. Changes to the Source Data and/or Location after Site Initiation Visit**

Capture here any changes occurred after the Site Initiation Visit (e.g., additional source data resulting from Amendments, changes to the SD location)

| ***Source Data*** | ***Provide Original Source Document Details:***  Provide details on the format/type of SD (e.g., medical chart, discharge summary, paper medical record, EMR) | ***Provide Original Source Document Location(s) at Site*:**  Specify where the Source may be found (e.g., specify which file; in whose office, which ward; Medical Records Department, EMR system at Imaging department, Lab, etc.)  原始数据存放位置发生更改时填写 | ***Comments/***  ***Additional Information***  E.g., indicate when certified copies will be provided to Monitor or how Monitor will access SDs in case read-only access to EMR system is not granted (i.e., over the shoulder monitoring - reviewing EMR while Investigator team member navigates the system); any relevant information about the SDs at site, as applicable | ***Investigator Signature & Date***  PI签字（英文拼音）及日期 |
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*Copy this page if needed*

**3. Site Close-out Visit**

By signing below, I confirm the following:

* I agree to archive all source documents (including certified copies of source documents used for monitoring purposes) and study-specific documentation and to retain them as required by ICH GCP and by the applicable local regulatory requirements

项目结束时PI签字和日期，使用英文拼音

* The source documents will be archived at the following location: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| --- | --- | --- |
| **Investigator’s Name:** | **Investigator’s Signature:** | **Date Signed:** |