**1. Study Details**

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| --- | --- | --- | --- |
| **Client:** | Chugai Pharmaceutical Co., Ltd. | **Principal Investigator:** |  |
| **Protocol Number:** | EDR2201CN | **Site Number:** | PI填写:启动会日期 |

**2. Site Initiation Visit**

As the Principal Investigator (PI) for the above-cited protocol, I have authorized the following staff to assume the indicated study tasks, for which they are qualified by training, education and experience, during the Site Initiation Visit (SIV) dated \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

I understand that the delegation of these tasks in no way alters my responsibilities as PI for this study as defined by ICH GCP, applicable regulations, and the clinical trial agreement.

PI填写：PI 签名（英文中文都签一个）

PI填写:启动会日期

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **To be signed and dated at the end of the SIV** | | | | | |
| **PI Name:**  **(Printed)**  Latin Alphabet | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.  PI填写：PI 英文首字母缩写 | **PI Signature:**  Local Alphabet | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. |  |  |
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| **PI Initials:** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. | **Date:** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. |  |  |
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**3. Study Tasks Matrix**

| **Role**  **Tasks** | **PI** | **Sub-I**  **(Physician)** | **Study**  **Coordinator (SC)** |  |  | 研究人员职责，可由PI或CRA填写或打印 |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Conduct Informed Consent Process |  |  |  |  |  |  |  |  |  |  |  |  |
| Sign Informed Consent |  |  |  |  |  |  |  |  |  |  |  |  |
| Determine Subject Eligibility |  |  |  |  |  |  |  |  |  |  |  |  |
| Document Medical History |  |  |  |  |  |  |  |  |  |  |  |  |
| AEs/ SAEs Assessments |  |  |  |  |  |  |  |  |  |  |  |  |
| Perform Medical Assessments (e.g., Physical Exam, Vital Signs) |  |  |  |  |  |  |  |  |  |  |  |  |
| CRF /eCRF - Data Entry/ Correction/ DCFs |  |  |  |  |  |  |  |  |  |  |  |  |
| CRF /eCRF - Review/Sign |  |  |  |  |  |  |  |  |  |  |  |  |
| Maintain ISF Documentation / IRB Communication |  |  |  |  |  |  |  |  |  |  |  |  |
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**4. Site Staff List**

职责，可由研究人员填写或打印

含PI，Sub-I，CRC，SN，pharmacist（药师）

QC等

被授权人填写，英文缩写

被授权人填写，名字，中英文均有，可打印

被授权人填写：签名，中英文均有

若授权是启动会当天，PI在involved since SIV处打勾或打叉（无需填写start date）并在PI initial写姓名缩写

As the Principal Investigator (PI) for this study, I have authorized the following site staff to assume the indicated study tasks for which they are qualified by training, education, and experience. I understand that the delegation of these tasks in no way alters my responsibilities as PI for this study as defined by ICH GCP, applicable regulations, and the clinical trial agreement.

| **Name (Printed):** | **Role (Printed)**  Sub-I, Study Coordinator, *etc*.  (Roles must match those outlined in the Study Task Matrix) | **Signature** | **Signed**  **Initials** | **Start Date**  If the staff team member was present during SIV, the box below should be marked, and the Start Date and PI Initials details left blank. | **Stop Date**  If the staff team member participated on the study to COV, the box below should be marked, and the Stop Date and PI Initials details left blank. |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  | **Involved since SIV:**  **Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Involved to COV:**  **Stop Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
|  |  |  |  | **Involved since SIV:**  **Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Involved to COV:**  若授权非启动会当天，PI在填写start date（无需involved since SIV处打勾或打叉）并在PI initial写姓名缩写  **Stop Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
|  |  |  |  | **Involved since SIV:**  **Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Involved to COV:**  **Stop Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
|  |  |  |  | **Involved since SIV:**  **Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Involved to COV:**  **Stop Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
|  |  |  |  | **Involved since SIV:**  **Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Involved to COV:**  **Stop Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
|  |  |  |  | **Involved since SIV:**  **Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Involved to COV:**  **Stop Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
|  |  |  |  | **Involved since SIV:**  **Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Involved to COV:**  **Stop Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
|  |  |  |  | **Involved since SIV:**  **Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Involved to COV:**  **Stop Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
|  |  |  |  | **Involved since SIV:**  **Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Involved to COV:**  **Stop Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** |
|  |  |  |  | **Involved since SIV:**  **Start Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** | **Involved to COV:**  **Stop Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Initials: \_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**5. Change of Principal Investigator**

此处在更换PI时才需要填写

**Outgoing Principal Investigator’s declaration:**

As the outgoing Principal Investigator (PI) for this study, I formally transfer all PI responsibilities to Dr. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, qualified by education, training and experience to take over this study role.

I confirm that I have performed an appropriate study handover which has included a review of the study protocol and procedures, the structure and functioning of the site team, and the interactions and tasks related to the Client, CRO and other third party service providers.

**Incoming Principal Investigator’s declaration:**

As the incoming PI for this study, I formally agree to assume all responsibilities from the outgoing PI, Dr.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

I have been fully informed regarding the study protocol and procedures, the structure and functioning of the site team, and the interactions and tasks related to the Client, CRO and other third party service providers. I accept the study site team as delegated by the outgoing PI and confirm that they are qualified by education, training, and experience to perform the tasks delegated to them.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of Transfer of Responsibilities:** | |  |  |  |  | | --- | --- | --- | --- | | |  | | --- | |  | |  | Thought Bubble: Cloud: 若授权是启动会当天，PI在involved since SIV处打勾或打叉（无需填写start date）并在PI initial写姓名缩写 | | |  | Thought Bubble: Cloud: 若授权是启动会当天，PI在involved since SIV处打勾或打叉（无需填写start date）并在PI initial写姓名缩写 | |

更换PI时，离开项目的PI签字和日期

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Outgoing PI’s Signature(s)** | | | | | |
| **PI Name:**  **(Printed)**  Latin Alphabet | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. | **PI Signature:**  Local Alphabet | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. |  |  |
|  |  |  |  |  |  |
| **PI Initials:** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | **Date:** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. |  |  |
|  |  |  |  |  |  |
| **Incoming PI’s Signature(s)**  更换PI时，新加入项目的PI签字和日期 | | | | | |
| **PI Name:**  Latin Alphabet | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. | **PI Signature:**  Local Alphabet | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. |  |  |
|  |  |  |  |  |  |
| **PI Initials:** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. | **Date:** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. |  |  |
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**6. Site Close-Out Signature**

As the Principal Investigator (PI) for this study, I confirm that the information in this form is correct, complete, and up to date.

此处在COV时才需要填写

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **To be signed and dated by the PI at the end of the Site Close-Out Visit** | | | | | |
| **PI Name:**  Latin Alphabet | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. | **PI Signature:**  Local Alphabet | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. |  |  |
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|  |  | **Date:** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. |  |  |
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