|  |  |  |  |
| --- | --- | --- | --- |
| Joint Research & Enterprise ServicesGround Floor, Jenner Wing, City St George’s University of London, Cranmer Terrace, Tooting, London SW17 0RE | | | |
| **JRESDOC0128**  **Principal Investigator Responsibilities Agreement for Clinical Trials of Investigational Medicinal Products (CTIMPs)** | | | |
| **Version number:** | Version 2.0 | **Date:** | 16/08/2024 |
| **JRES Number & Short**  **Study Title:** |  | **Site Name & Number** |  |
| **EudraCT Number:** |  | **Chief Investigator (CI):** |  |

*This agreement outlines the responsibilities of the Principal Investigator for CTIMPs as defined by the Medicines for Human Use (Clinical Trials) Regulations 2004, sponsored by City St George’s University of London or St George’s University Hospitals NHS Foundation Trust.*

|  |  |
| --- | --- |
| **1. Sponsorship and R&D** | |
| **1.1** | Ensuring that the trial does not commence until Sponsor and R&D (host site) approval are granted. |
| **1.2** | Ensuring that all clinical trial proposed amendments (substantial or non-substantial) sent by the Sponsor are reviewed by the R&D (host site). |
| **1.3** | Ensuring that R&D (host site) approval of relevant amendment(s) is obtained prior to its implementation. |
| **1.4** | Assisting with inspections, audits and monitoring of the study whether these are conducted by the Sponsor or a third party. In addition, ensure that audit results from third parties relating to the study are made available to the Sponsor. |
| **1.5** | Ensuring any monitoring/audit queries are responded to according to the timelines set out in the monitoring and audit reports. |
| **2. Good Clinical Practice (GCP) Compliance** | |
| **2.1** | Ensuring that all members of the research team conduct the clinical trial in compliance with the study Protocol, Good Clinical Practice (GCP), relevant Sponsor’s SOPs, local policies and relevant legislation |
| **2.2** | Ensuring members of the research team are suitably trained on the Protocol prior to performing clinical trial activities. |
| **2.3** | Ensuring members of the research team hold current Good Clinical Practice (GCP) certificates prior to working on the clinical trial. |
| **2.4** | Ensuring all members of staff consenting participants are appropriately trained, participants are eligible and are consented following GCP. |
| **2.5** | Setting up and maintaining the Investigator Site File (ISF), ensuring that it contains all essential documents as outlined in the Sponsor’s Index and making sure it is available for inspection if and when requested. |
| **2.6** | Ensuring that a copy of the Sponsor’s Delegation of Responsibilities and Signature Log is completed and signed by all members of the investigator team. |
| **2.7** | Ensuring that all trial documentation is version-controlled at all times. |
| **3. Pharmacovigilance** | |
| **3.1** | Ensuring that all SAEs are reported to the Sponsor, in line with the Sponsor’s SOP and the study protocol. |
| **3.2** | Ensuring that all AEs/SAEs/ are recorded in line with the Sponsor’s SOP and the study protocol. |
| **3.3** | Maintain records of all communication relating to SAEs |
| **3.4** | Recording and promptly reporting all Suspected Unexpected Serious Adverse Reactions (SUSARs) to the Sponsor according to the Sponsor’s SOP and the study protocol. |
| **3.5** | Ensuring the ongoing safety and well-being of the trial participants at the trial site and implementing Urgent Safety Measures where required. |
| **4. Clinical Trial Conduct** | |
| **4.1** | Notifying the Sponsor of the date of the first signed consent form. |
| **4.2** | Keeping a record of all screened patients, consented patients and withdrawals using the Sponsor’s Log provided during the Site Initiation Visit. |
| **4.3** | Ensuring trial data is recorded, handled, stored and reported accurately and confidentially. |
| **4.4** | Ensuring that trial case report forms (CRFs) are completed as fully as possible, submitted in a timely manner and any corrections are made within the specified timeframe. |
| **4.5** | Notifying any pregnancies to the sponsor as soon as possible and request consent for the follow up of the pregnancy from the trial participant (or their partner). |
| **4.6** | Ensuring that any deviations from the protocol, GCP and applicable regulatory requirements are communicated to the Sponsor and implement any corrective and preventative actions. |
| **4.7** | Reporting any potential serious breaches to the Sponsor to enable their review and reporting to the REC and MHRA |
| **4.8** | Ensuring satisfactory IMP management and accountability at the site and that the IMP is not used for any purposes other than in strict accordance with the Protocol. |
| **4.9** | Ensuring that participants are randomised in line with the protocol and receive the allocated treatment. |
| **4.10** | Ensuring that code break procedures are followed should unblinding be necessary. |
| **4.11** | Ensuring that all essential trial documents are filed and archived according to local procedures. |

The Sponsor retains the right to withdraw or suspend site participation for the clinical trial at any time if deemed necessary. In acknowledgement of the above-mentioned responsibilities both the Sponsor’s representative and PI should sign below.

|  |  |  |  |
| --- | --- | --- | --- |
| Signed on Behalf of Sponsor | | Site’s Principal Investigator (PI) | |
| Name: |  | Name: |  |
| Title: |  | Title: |  |
| Signature |  | Signature |  |
| Date (dd/mm/yyyy): |  | Date (dd/mm/yyyy): |  |