Responsibilities delegated to the Chief Investigator for CTIMP and/or CIMD Trials Sponsored by NHS Greater Glasgow & Clyde

Study Title:

ISRCTN No.:

Chief Investigator:

|  |
| --- |
| Under the co-sponsorship arrangement, the Chief Investigator is required to:  **(From decision to sponsor until R&I approval)** |
| 1. Attend a **risk assessment meeting** with Sponsor representatives and other TMG members to discuss the risks involved in the study and how these can be mitigated. |
| 1. Ensure that he/she and all the research team know the principles of **GCP and key legislation** as appropriate and have received appropriate trial-specific and GCP training. |
| 1. Ensure his/her research team have the **necessary resources, expertise, experience and education** to perform their roles to the required standards. |
| 1. Ensure the **eCRF** development is appropriate for the trial data and is suitable for the Sponsor stakeholder requirements such as PV, pharmacy and monitoring. |
| 1. Working with Sponsor Reps, ensure that **Ethical approval, MHRA approval and local permissions/approvals** are in place before recruitment begins. |
| ***(During the Trial)*** |
| 1. Ensure all Glasgow Health Science Partnership Board (GHSP Board) and clinical trial-specific **SOPs and guidance**, identified as relevant to the CI and/or study are adhered to throughout the life of the project and complete the required training records for these SOPs. |
| 1. Ensure continuous assessment of **developments in guidance, literature and practice** in the field of research, with a view to consider the ongoing risk-benefit of the study and bring any required updates to the attention of the Sponsor. |
| 1. Ensure **risk is continuously assessed**, and any new risks are highlighted to Sponsor representatives and other TMG members to discuss how these can be mitigated. |
| 1. Confirm, as specified in the site agreement an up to date **trial-specific training log** of all personnel selected for and trained to work on the trial and ensure that their delegated duties are recorded and kept up to date in a **trial delegation log**. |
| 1. Confirm, as delegated to the study Project Manager, all new staff are provided with **trial-appropriate** training and details of this are recorded in the study site file. |
| 1. Ensure that **consent is given freely and in writing** from all subjects or the subject’s legal representative before they are involved in any trial procedures. |
| 1. Ensure all **trial-related medical decisions** are made by an appropriately **qualified healthcare professional**. |
| 1. Ensure that **Case Report Forms** are completed accurately and that adverse events are recorded fully. Any corrections on this documentation must adhere to good document management practice. |
| 1. Ensure that all data are collected, used and stored in accordance with the **Data Protection Act (2018) and are compliant with GDPR.** |
| 1. Ensuring trial procedures for **reporting SAE and SUSARs** are followed within the time frames required by law and as outlined in the protocol. |
| 1. Ensure all **proposed amendments** to the trial protocol are discussed, reviewed and approved by Sponsors before being submitted to REC and MHRA (and any other relevant committees). All relevant amendment approval/permissions should be received prior to amendment implementation. |
| 1. Ensure that the University are kept informed of any amendments to the protocol so that **adequate insurance** can be maintained throughout the trial duration. |
| 1. Ensure that **all potential trial sites** are discussed with the **TMG** so that appropriate contractual arrangements can be put in place. |
| 1. Ensure that **the REC and the MHRA** are informed of all **new trial sites**. |
| 1. Submit an **annual safety report** to the Sponsor and MHRA 12 months after the date on which favourable opinion was given and ensure that the reports are submitted thereafter until the end of the study. |
| ***(During close-down)*** |
| 1. Notify **the MHRA and the REC** of the **end of the trial** within 90 days if the trial runs to the planned completion date and within 15 days if stopped prematurely. |
| 1. Must provide the **Final Report** of the trial to the main REC and MHRA within 1 year of the end of the trial. |
| 1. Must ensure that trial records are **archived** in accordance with the protocol. |
| 1. Ensure that ISRCTN (or other appropriate) registry is updated with study results. |
| ***(Throughout the course of the trial and until records are destroyed)*** |
| 1. Allow access to the **Site Files** and all trial-associated documents to **Auditors and Monitors** on request. |
| 1. Facilitate **statutory inspections** by assisting with the audit of **TMF** and trial-associated documentation. |
| **By signing this document you confirm that you understand your obligations and that you will carry them out to the required standards. This includes reading and following the list of Sponsor-defined CI Standard Operating Procedures (please see below list of current CI SOPs) available on the Glasgow CTU website:** [**https://www.glasgowctu.org/Home/sops/**](https://www.glasgowctu.org/Home/sops/)  **All relevant SOPs must be read before signing.** |
| CI Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name (PRINTED): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Sponsor Defined CI Standard Operating Procedures**

This list is accurate at the time of release of this form, the master list is controlled through Q-Pulse and the relevant SOPs will be distributed to all CIs for them to read and record they have done so through Q-Pulse.

|  |  |
| --- | --- |
| **Number** | **Title** |
| SOP 50.013 | Setup and Maintenance of Training Files: NHS |
| SOP 50.020 | eCRF User Acceptance Testing (Glasgow Clinical Trials Unit) |
| SOP 51.001 | Protocol Development |
| SOP 51.002 | Participant Information Sheet and Consent Forms: Design and Approval |
| SOP 51.004 | Risk Assessment |
| SOP 51.007 | Identifying a Sponsor organisation |
| SOP 51.008 | Handling Non-Compliance with Good Clinical Practice (GCP) and/or The Trial Protocol in Clinical Research Sponsored, Co-Sponsored or Hosted by NHS Greater Glasgow and Clyde |
| SOP 51.014 | Preparation and submission of IRAS forms |
| SOP 51.017 | Registration of research projects on public databases |
| SOP 51.019 | Sponsor – End of Study Procedures |
| SOP 51.021 | Review and Approval of Amendments for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow |
| SOP 51.023 | Sponsor process for an IDMC |
| SOP 51.024 | Archiving Essential Documents from Clinical Research – Process for a Sponsored Clinical Trial of an Investigational Medicinal Product (CTIMP) and/or Clinical Investigation of a Medical Device (CIMD) |
| SOP 51.028 | NHS Laboratory samples for Research Sponsored by NHSGGC or Co-sponsored by NHSGGC and the University of Glasgow or hosted by NHSGGC |
| SOP 51.029 | Writing Study Specific Laboratory Manuals for Trials involving Investigational Medicinal Products sponsored by NHS GG&C or Co-sponsored by NHS GG&C and the University of Glasgow |
| SOP 51.030 | Writing Sample Handling Manuals for Sites Participating Research Sponsored by NHSGGC or Co-sponsored by NHSGGC and University of Glasgow |
| SOP 51.033 | Research Imaging for Trials involving an Investigative Medicinal Compound (CTIMP) Sponsored by NHS GG&C or Co-sponsored by NHS GG&C and the University of Glasgow (UoG) |
| SOP 51.034 | Writing a Trial Specific Research Imaging Manual for Sites Participating in Clinical Trials of an Investigative Medicinal Product (CTIMP) Sponsored by NHS GG&C or Co-sponsored by NHS GG&C and University of Glasgow (UoG) |
| SOP 51.035 | Design and Development of CRFs/eCRFs in CTIMPs and Clinical Investigations |
| SOP 51.036 | Trial Steering Committee for Trials involving an Investigative Medicinal Compound (CTIMP) Sponsored by NHS GG&C or Co-sponsored by NHS GG&C and the University of Glasgow |
| SOP 51.037 | Storage and Transfer of Laboratory Data for Clinical Trials and Investigations Sponsored by NHS Greater Glasgow & Clyde (NHS GG&C) or Co-Sponsored by NHS GG&C & University of Glasgow |
| SOP 53.002 | The Handling of Poor Quality and Fraud in Clinical Research |
| SOP 53.003 | Temporary halt or early termination of clinical trials of investigational medicinal products |
| SOP 55.001 | Pharmacovigilance in Clinical Trials of Investigational Medicinal Products (Glasgow Clinical Trials Unit) |
| SOP 55.002 | Preparation and submission of the Development Safety Update Report |
| SOP 55.004 | Safety RepSafety Reporting Requirements for Research Other Than Clinical Trials of Investigational Medicinal Products and non CE Marked Medical Devices |
| SOP 55.006 | Selection and Periodic Review of IBs and SmPCs in CTIMPs for Clinical Management |
| SOP 55.007 | Safety Reporting in Clinical Trials of Medical Devices of Non CE Marked Medical Devices or CE Marked Devices Used Outside of their Intended Purpose (Sponsored and Hosted Clinical Investigations) |
| SOP 58.004 | Clinical Research Involving Imaging |

|  |
| --- |
| This Form is a controlled document. The current version can be viewed on the GCTU website.  Any copy reproduced from the website may not, at time of reading, be the current version. |