**Memorandum of understanding (MoU) for Clinical Trial Delegation of Sponsorship Responsibilities**

between

**[NAME OF SPONSOR]**, of [INSERT ADDRESS]

 (hereinafter referred to as “the Sponsor”)

AND

**[NAME OF TRIALS UNIT]**, of [INSERT ADDRESS]

(hereinafter referred to as “INSERT NAME”)

AND

**[NAME OF CI]**, of [INSERT ADDRESS] (hereinafter referred to as the “Chief Investigator”)

for the conduct of the Clinical Trial entitled ***[INSERT TITLE]*** (“the Clinical Trial”)

|  |  |
| --- | --- |
| Sponsor number: |  |
| EudraCT number: |  |

[INSERT NAME OF TRIALS UNIT] and the Chief Investigator have sufficient knowledge and experience to conduct this Clinical Trial.

The purpose of the MoU is set out the respective roles and responsibilities of the Sponsor, [INSERT NAME OF TRIALS UNIT] and the Chief Investigator.

The Sponsor, [INSERT NAME OF TRIALS UNIT] and the Chief Investigator shall undertake the responsibilities set out below.

Where responsibilities are further delegated to another member of the Trial team, that individual must receive sufficient support and training to fulfil that role and all delegated duties must be detailed within the Trial Master File held at [INSERT NAME OF TRIALS UNIT] and the Trial Site File held at the participating centre.

**SPONSORSHIP AND RESPECTIVE RESPONSIBILITIES**

|  | **Sponsor [Name of Sponsor]** | **[NAME OF TRIALS UNIT] CTU** | **Chief Investigator** | **Participating Site**  | **Principal Investigator (PI)** |
| --- | --- | --- | --- | --- | --- |
| **1**  | **Sponsorship** |  |  |  |  |
|  1 | Undertake role of Sponsor as defined by the UK Policy Framework for Health and Social Care Research and the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended. |  |  |  |  |
|  2 | Responsibility for the liability and indemnity for the Clinical Trial as defined under UK regulations and the Protocol |  |  | Provision of NHS Indemnity for Research Team and any other Trial site employee, consultant and/or agent involved in the Clinical Trial |  |
|  3 | Appoint an individual to represent the Sponsor’s interests for the duration of the Clinical Trial on the Data Monitoring Committee |  |  |  |  |
|  4 | Ensure the trial team will be able to access adequate resources and support to deliver the trial |  |  |  |  |
|  |  |  |  |  |  |
| 2  | **Permissions and notifications** |  |  |  |  |
|  1 | Approval and sign off the application to the main research ethics committee (REC). | Managing the application for the main REC opinion | Sign off the application to the main REC. |  |  |
|  2 |  | Managing the request for authorisation to conduct the Clinical Trial made to the licensing authority (MHRA). | Sign off request for authorisation to conduct the Clinical Trial made to the MHRA. |  |  |
|  3 | Approve all amendments to the CTA | To notify the MHRA of amendments to the CTA which includes an amendment to—1. The terms of the request for authorisation of the Clinical Trial; or
2. The particulars or documents that accompanied that request
 | Sign off the notification of amendments to MHRA. |  |  |
|  4 | Approve all amendments to the REC application | Notify the REC of amendments to the favourable opinion which includes an amendment to—1. The terms of the application for REC opinion; or
2. The particulars or documents that accompanied that application
 | Sign off notification of amendments to REC. |  |  |
|  5 |  | Notify MHRA, REC and Sponsor that the trial has ended within 90 days of the conclusion of the Clinical Trial |  |  | End of Clinical Trial notification to local R & D Office. |
|  6 |  | Notify MHRA, REC and Sponsor within 15 days if the Clinical Trial is terminated—1. Before the date for the conclusion of the Clinical Trial specified in the Protocol, or
2. Before the event specified in the Protocol as the event which indicates the end of the trial has occurred.
 |  |  | End of Clinical Trial notification to local R & D Office. |
|  7 | Assess all potential Serious breaches of GCP. Notify MHRA in writing of any actual serious breach of—1. the conditions and principles of GCP in connection with the trial
2. the protocol relating to the trial

within 7 days of becoming aware of the same  | Notify Sponsor immediately of any potential Serious breaches of GCP. | Notify [NAME OF TRIALS UNIT] immediately of any potential Serious breaches of GCP. | Notify [NAME OF TRIALS UNIT] immediately or within 24 hours of becoming aware of any potential Serious breaches of GCP. | Notify [NAME OF TRIALS UNIT] immediately or within 24 hours of becoming aware of any potential Serious breaches of GCP. |
|  8 |  | Provide the REC with an annual progress report | Sign off the annual progress report |  | Provision of annual reports, including safety reports, as required, to R & D. |
|  9 | Notify [NAME OF TRIALS UNIT] re Clinical Trial Site Agreements that are complete to enable [NAME OF TRIALS UNIT] to open up Trial Sites for recruitment | Ensure participating Trial Site selection and registration process as described in the Protocol is complete before Clinical Trial commences at each Site. Provide the participating Site with any trial-related REC and MHRA documentation required by the Site for R&D and Site Specific Assessment approval |  | Obtain R&D approval and Site Specific Assessment approval for the Clinical Trial (including approval of any amendments) and provide copies of the associated documentation to the [NAME OF TRIALS UNIT], ensuring provision of adequate resources locally to conduct the Clinical Trial | Application to local R&D Office for host organisation approval (including amendments) and completion of the Trial Site Registration process described in Protocol |
|  |  |  |  |  |  |
| 3  | **Trial Management** |  |  |  |  |
|  1 |  | Appoint and coordinate a Clinical Trial management group (TMG) to consider day-to-day management issues and the overall progress of the Clinical Trial | Chair the TMG |  |  |
|  2 |  | Convene a Trials Steering Committee (TSC) to provide oversight of the trial |  |  |  |
|  3 |  | Convene a data monitoring committee (DMC) to receive and review the progress and accruing data of the Clinical Trial and provide advice on the conduct of the trial to Sponsor and the TSC |  |  |  |
|  4 |  | To co-ordinate any other Clinical Trial committee and management activities specified in the Clinical Trial Protocol |  |  |  |
|  |  |  |  |  |  |
| 4  | **Conduct of the Trial** |  |  |  |  |
|  1 | Ensure the conduct of Clinical Trial is in accordance with GCP and applicable Regulations | Ensure the conduct of Clinical Trial is in accordance with GCP and applicable Regulations | Ensure the conduct of Clinical Trial is in accordance with GCP and applicable Regulations | Ensure the conduct of Clinical Trial is in accordance with GCP and applicable Regulations | Ensure the conduct of Clinical Trial is in accordance with GCP and applicable Regulations |
|  2 |  | Review all protocol deviations/instances of non-compliance and take appropriate corrective and preventative action | Review all protocol deviations/instances of non-compliance and take appropriate corrective and preventative action |  |  |
|  3 | Verify that the Trial Master File has all essential documents in place prior to Clinical Trial commencement | Maintain TMF. |  |  |  |
|  4 |  | Ensure the conduct of Clinical Trial is in accordance with—1. the Protocol
2. the terms of the—
	1. CTA (where applicable)
	2. REC approval
	3. Other approvals as required
 | Adhere to the Protocol and other Clinical Trial documentation | Adhere to the Protocol and other Clinical Trial documentation | Adhere to the Protocol and other Clinical Trial documentation |
|  5 |  | Prepare standard operating procedures (SOPs) identified as necessary to manage the Clinical Trial |  |  |  |
|  6 | Maintain central SOPs and make available to CI | Receive, read and follow all relevant central SOPs |  |  |  |
|  7 | Receive Clinical Trial SOPs and review and approve Clinical Trial SOPs where appropriate | Review and approve Clinical Trial SOPs |  |  |  |
|  8 |  | Follow all processes and procedures as defined by [NAME OF TRIALS UNIT] authorised SOPs  | Follow all processes and procedures as defined by [NAME OF TRIALS UNIT] authorised SOPs | Follow all processes and procedures as sent by [NAME OF TRIALS UNIT]  | Follow all processes and procedures as sent by [NAME OF TRIALS UNIT] |
|  9 | Review Sponsor registration form, finalised Protocol and participant information prior to REC submission |  |  |  |  |
|  10 |  | Ensure CI, all researchers involved and participating Sites and staff are aware of, trained in and complying with Clinical Trial specific SOPs, via trial initiation meeting, or alternative means, as deemed appropriate | Assist in Clinical Trial Initiation training | Identification of a suitably qualified clinician to carry out the role of Local Principal Investigator, to take overall responsibility for leading the Clinical Trial at the Trial Site.  | Formal delegation of duties to the Research Team and/or any other appropriately qualified and experienced staff. |
|  11 |  |  |  | Ensure Research Team and/ or any other employee, honorary employee, agent, consultant at the Trial Site are appropriately qualified and experienced and have received suitable training. | Ensure Research Team and/ or any other employee, honorary employee, agent, consultant at the Trial Site are appropriately qualified and experienced and have received suitable training. |
|  12 |  | Inform the participating Trial Site and the Local PI of the name and telephone number of the trial manager and the Sponsor’s representative. |  |  |  |
|  13 |  | Appoint a Trial Manager with suitable qualifications, training and experience to act as the principal contact for participating Trial Sites. The Trial Manager shall also act as the document controller, responsible for the dissemination of the research Protocol, Protocol amendments, associated trial documentation and trial specific SOPs to the document controller at the specific Clinical Trial Site |  |  | Identify a Trial Site contact to act as document controller to take responsibility for receipt and dissemination locally of research Protocol, Protocol amendments, associated Clinical Trial documentation and trial specific SOPs |
|  14 |  | Appoint a Senior Statistician, and where appropriate, a Data Manager and/or Trial Assistant, with suitable qualifications, training and experience to support the Trial Manager in Clinical Trial conduct. |  |  |  |
|  15 |  |  |  |  | Provision of written information to Clinical Trial Participants on Trial Site headed paper, and obtaining written informed consent prior to the Clinical Trial Participant taking part in the Clinical Trial. |
|  16 | Implement adequate business continuity / disaster recovery plans to ensure recovery and restoration of critical trial functions following unforeseen disasters or extended disruption | Implement adequate [NAME OF TRIALS UNIT] business continuity / disaster recovery plans to ensure recovery and restoration of critical trial functions following unforeseen disasters or extended disruption |  |  |  |
|  17 |  | Ensuring regulatory and Protocol compliant randomisation and/or registration into Clinical Trial |  | Ensuring regulatory and Protocol compliant randomisation and/or registration into the Clinical Trial | Ensuring regulatory and Protocol compliant randomisation and/or registration into the Clinical Trial |
|  18 |  | To ensure that any Clinical Trial samples are collected, processed, shipped and stored as described in the Protocol and as per regulatory requirements. |  | To ensure that any Clinical Trial samples are collected, processed, shipped and stored as described in the Protocol and as per regulatory requirements. | To ensure that any Clinical Trial samples are collected, processed, shipped and stored as described in the Protocol and as per regulatory requirements. |
|  19 |  |  | Act as sample custodian for all samples received by sponsor. |  | Local PI to maintain records of all samples collected, including details as to their preparation, separation, shipping (or disposal if relevant) and ensuring that each shipment is accompanied by relevant paperwork (with a copy to be retained by the local PI) including details of the sample numbers, number of samples transferred, distribution and location of the samples transferred. |
|  20 | To ensure completion of all other Clinical Trial conduct and monitoring as described in the Protocol. | To ensure completion of all other Clinical Trial conduct and monitoring as described in the Protocol. | To ensure completion of all other Clinical Trial conduct and monitoring as described in the Protocol. | To ensure completion of all other Clinical Trial conduct and monitoring as described in the Protocol. | To ensure completion of all other Clinical Trial conduct and monitoring as described in the Protocol. |
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| 5  | **IT/Data** |  |  |  |  |
|  1 |  | Ensure IT systems and processes are set up and maintained to ensure data integrity and archiving to adequate regulatory requirements including, but not limited to, database set up and hosting and IT security |  |  |  |
|  2 |  |  | Take on the role of Data Custodian |  |  |
|  3 |  | Ensuring regulatory and GCP compliant Clinical Trial Data management including, but not limited to, CRF movement, databases and data handling and following up data queries. |  |  | Accurate and timely submission of Clinical Trial Data as specified in the Protocol and this Site agreement, including timely response to queries. |
|  |  |  |  |  |  |
| 6  | **Trial Documentation (inc Trial Master File (TMF), protocol, CRFs, PIS)** |  |  |  |  |
|  1 | Keep a Sponsor TMF for the Clinical Trial containing the essential documents relating to the Clinical Trial | Keep a TMF for the Clinical Trial containing the essential documents relating to the Clinical Trial, including a sample Site File and key correspondence with Sites. Ensure that essential documentation is forwarded to the Sponsor and PIs for filing in the TMF and PI Site File (ISF) respectively in a timely manner and as appropriate. |  | Keep a local Site File for the Clinical Trial containing the essential documents relating to the Clinical Trial | Keep a Investigator Site File for the Clinical Trial containing the essential documents relating to the Clinical Trial |
|  2 | Ensure that the TMF (and other appropriate Clinical Trial files) is readily available at all reasonable times for inspection by the licensing authority or any person appointed by the Sponsor to audit the arrangements for the Clinical Trial | Ensure that the TMF (and other appropriate Clinical Trial files) is readily available at all reasonable times for inspection by the licensing authority or any person appointed by the Sponsor to audit the arrangements for the Clinical Trial |  | Ensure the Investigator Site File (and other appropriate Clinical Trial files including but not limited to any Clinical Trial participant medical records) is readily available at all reasonable times for inspection by the licensing authority, the [NAME OF TRIALS UNIT], or any person appointed by the Sponsor to audit the arrangements for the Clinical Trial | Ensure the Investigator Site File (and other appropriate trial files including but not limited to Clinical Trial Participant medical records) is readily available at all reasonable times for inspection by the licensing authority, the [NAME OF TRIALS UNIT], or any person appointed by the Sponsor to audit the arrangements for the Clinical Trial |
|  3 |  | Design the research Protocol describing the objectives, design, methodology , statistical considerations and organisation of the Clinical Trial | Design the research Protocol describing the objectives, design, methodology , statistical considerations and organisation of the Clinical Trial |  |  |
|  4 |  | Prepare documentation to assist with the organisation, management and conduct of the Clinical Trial. This documentation includes but is not limited to, Participant information sheets, consent forms, case report forms, Clinical Trial Participant diaries etc. | Prepare documentation to assist with the organisation, management and conduct of the trial. This documentation includes but is not limited to, participant information sheets, consent forms, case report forms, Clinical Trial participant diaries etc. |  |  |
|  |  |  |  |  |  |
| 7  | **Contracts** |  |  |  |  |
|  1 | Use a Clinical Trial Agreement to form the agreement between sponsor and collaborating NHS Sites (model UKCRC agreement are preferable) |  |  | Sign the Clinical Trial Agreement as part of the Site initiation process |  |
| 2 | Ensuring that appropriate written agreements are in place between the Sponsor and any organizations carrying out duties on a ‘sub-contractual’ basis (including IMP supply agreements) | Provide input into the negotiation of the contracts | Provide input into the negotiation of the contracts |  |  |
| 3 | Subject to the provision of Clause [INSERT CLAUSE] of Site Agreement ensure that a formal letter of Agreement is in place between the Trial Site and any hospital where applicable including identifying respective roles and responsibilities for Clinical Trial conduct, and if appropriate, patient care |  |  |  |  |
|  |  |  |  |  |  |
| 8  | **Pharmacovigilance** |  |  |  |  |
|  1 | Make appropriate urgent safety measures in order to protect the Clinical Trial Participants of a Clinical Trial against any immediate hazards to their health or safety | Make appropriate urgent safety measures in order to protect the participants of a Clinical Trial against any immediate hazards to their health or safety | Make appropriate urgent safety measures in order to protect the participants of a Clinical Trial against any immediate hazards to their health or safety | Make appropriate urgent safety measures in order to protect the Clinical Trial Participants against any immediate hazards to their health or safety | Make appropriate urgent safety measures in order to protect the Clinical Trial Participants against any immediate hazards to their health or safety |
|  2 | Report Urgent Safety measures to [NAME OF TRIALS UNIT]  | Notify MHRA and REC of Urgent Safety measures | Report Urgent Safety measures to [NAME OF TRIALS UNIT] | Report Urgent Safety measures to [NAME OF TRIALS UNIT] | Report Urgent Safety measures to [NAME OF TRIALS UNIT] |
|  3 |  | Keep detailed records of all SAEs as required by the Protocol which are reported by the Principal Investigators for the Clinical Trial | Assessment of SAEs |  | Report any adverse event which occurs in a Clinical Trial Participant at the Trial Site in accordance with the procedure described in the Protocol |
|  4 |  | Notify Sponsor of SAEs within [INSERT TIMEFRAME] |  |  |  |
|  5 |  | Ensure that Suspected Unexpected Serious Adverse Reactions (SUSARs) are—1. recorded; and
2. reported to—
	1. the licensing authority,
	2. the relevant REC,
	3. IMP supply companies,

and in any event not later than 7 days (fatal or life threatening) or 15 days (non-fatal or life threatening) after the first awareness of the reactionEnsure that within 8 days of a report any additional information is sent to the licensing authority and the relevant REC |  |  |  |
|  6 |  | Ensure that the Local PIs responsible for the conduct of Clinical Trial are informed of any SUSAR which occurs in relation to an IMP used in that Clinical Trial |  |  |  |
|  7 |  | As soon as practicable after the end of the reporting year provide the licensing authority and the relevant REC (and sponsor) with—1. a list of all suspected SARs which have occurred during that year, including those reactions relating to any IMP used as a placebo or as a reference in the Clinical Trial
2. a report on the safety of the participants in the Clinical Trial
 | Provide input and sign off for the list of suspected SARs and safety report. Confirm any changes (or not) to the risk:benefit for the trial. |  |  |
|  8 |  | As soon as practical after the end of the reporting year provide PIs at each of the Clinical Trial Sites a copy of the Annual Safety Report which includes a line listing of all Suspected Serious Adverse Reactions which have occurred during that year |  |  |  |
|  9 |  | Report Serious Adverse Events to the companies supporting trial as defined within the contract between Sponsor and company |  |  | Respond to requests for additional information for safety reports |
|  |  |  |  |  |  |
| 9  | **Monitoring** |  |  |  |  |
|  1 | Carry out monitoring of the [NAME OF TRIALS UNIT] and CI as required by the Trial Monitoring Plan. | Carry out central and Site monitoring on behalf of the Sponsor as required by the Trial Monitoring Plan. |  | Cooperate with and participate in any monitoring, audit or inspection visit | Cooperate with and participate in any monitoring, audit or inspection visit |
|  |  |  |  |  |  |
| 10  | **Archiving** |  |  |  |  |
|  1 | Ensure that all documents contained, or have been contained, in the Sponsor TMF are retained for at least 15 years after the conclusion of the Clinical Trial | Ensure that all documents contained, or have been contained, in the TMF are retained for at least 15 years after the conclusion of the Clinical Trial. Ensure that Clinical Trial Sites retain all documents contained in the Study Site File and patient CRFs for at least 15 years. |  | Ensure that all documents contained, or have been contained, in the local Principal Investigator Site File are retained for at least 15 years after the conclusion of the Clinical Trial | Ensure that all documents contained, or have been contained, in the local Principal Investigator Site File are retained for at least 15 years after the conclusion of the Clinical Trial |
|  2 |  |  |  |  | Ensure that the medical files of Clinical Trial Participants are retained for at least 15 years after the conclusion of the Clinical Trial |
|  3 |  | Appoint named individuals to be responsible for archiving the documents which are or have been contained in the TMF and, with the exception of the licensing authority and any person appointed by the Sponsor to audit the arrangements for the Clinical Trial Subject, access to those documents shall be restricted to those appointed individuals |  |  |  |
|  4 |  | Ensure secure restricted access (to delegated individuals) archiving space that meets regulatory requirements |  |  |  |
|  |  |  |  |  |  |
| 11  | **Quality Assurance** |  |  |  |  |
|  1 |  | Implement and maintain quality assurance and quality control systems with written SOPs to ensure that the Clinical Trial Participant is conducted and data generated, documented and reported in compliance with the Protocol, GCP and applicable regulatory requirements |  |  |  |
|  |  |  |  |  |  |
| 12  | **Reporting and finance** |  |  |  |  |
|  1 |  | Ensure reporting to relevant groups including but not limited to the funders, UKCRC, NCRN, and regulatory bodies, as per their requirements.  |  |  |  |
|  2 | Ensure grant funds are administered in accordance with the terms of the award, properly recorded and reported, and that requests to funders for renewal or re-allocation are made promptly |  | Ensure grant funds are administered in accordance with the terms of the award, properly recorded and reported, and that requests to funders for renewal or re-allocation are made promptly |  |  |
|  |  |  |  |  |  |
| 13  | **Statistics analysis and publication** |  |  |  |  |
|  1 |  | Ensuring regulatory and GCP compliant statistical arrangement including, but not limited to, design, statistical analysis and appropriate documentation |  |  |  |
|  2 |  |  | Responsibility for producing the first publication for the Clinical Trial Participant as per the Protocol | Responsibility not to publish any results of the Clinical Trial as per the Protocol until the CI/ Sponsor has made Formal Publication |  |
|  3 |  | Ensuring publication is sent for review to appropriate parties including but not limited to the Sponsor and [NAME OF TRIALS UNIT] and any party to whom the Sponsor has any legal obligations to give notice of publication |  |  |  |
|  4 | Ensuring confidentiality to a level dictated by regulatory requirement or imposed by Sponsor and/or funder, and within the legal obligations the Sponsor has regarding any Clinical Trial-related agreements  | Ensuring confidentiality to a level dictated by regulatory requirement or imposed by Sponsor and/or funder, and within the legal obligations the Sponsor has regarding any Clinical Trial -related agreements. Notify participating centres of any breaches of confidentiality. | Ensuring confidentiality to a level dictated by regulatory requirement or imposed by Sponsor and/or funder, and within the legal obligations the Sponsor has regarding any Clinical Trial -related agreements | Ensuring confidentiality to a level dictated by regulatory requirement or as imposed by Sponsor and/or Funder, and/ or in accordance with any legal obligations the Sponsor has in relation to any Clinical Trial -related agreements | Ensuring confidentiality to a level dictated by regulatory requirement or as imposed by Sponsor and/or Funder, and/ or in accordance with any legal obligations the Sponsor has in relation to any Clinical Trial -related agreements |
|  5 | Holder of any intellectual property – including power to delegate decision for Clinical Trial Data release, and within the legal obligations the Sponsor has regarding any Clinical Trial -related agreements  |  |  |  |  |
|  |  |  |  |  |  |
| 14  | **Drug and its movement** |  |  |  |  |
|  1 |  | To ensure that the Investigator’s Brochure (IB) is valid and updated at least once a year  |  |  |  |
|  2 |  | Provide Local PIs with (or link to) updated IB as necessary, and ensure that any confidentiality agreements required to allow Local PIs access to these documents are implemented. |  | To ensure that any confidentiality agreements required to allow the PI access to the IB are implemented. |  |
|  3 |  | Ensuring a regulatory compliant IMP handling/custody including, but not limited to, adequate QP release, documentation to ensure quality and certificate of analysis |  |  |  |
|  4 |  | Central IMP accountability, ordering and distribution |  | Keep records of deliveries, storage, administration, and where appropriate destruction, of IMPs and/or device and have in place a system that allows for the retrieval of defective IMPs. |  |
|  5 |  | Provide authorisation to Site to destroy expired and/or quarantined IMP stock. |  | Destruction of expired and/or quarantined IMP stock in accordance with instructions from [NAME OF TRIALS UNIT]. |  |
|  6 |  |  |  | Ensure that any IMPs and/ or devices used in the Clinical Trial are given to the Clinical Trial Participant free of charge, and are used solely for the purpose of the Clinical Trial. | Ensure that any IMPs and/ or devices used in the Clinical Trial are given to the Clinical Trial Participant free of charge, and are used solely for the purpose of the Clinical Trial. |
|  |  |  |  |  |  |

Signed in acknowledgement of the terms of this MoU

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| For and on behalf of the Sponsor | For and of behalf of [NAME OF TRIALS UNIT] | The Chief Investigator |
| Name: ………………………….. | Name: ………………………….. | Name: ………………………….. |
| Title: …………………………….. | Title: …………………………….. | Title: …………………………….. |
| Signature………………………… | Signature………………………… | Signature………………………… |
| Date: ……………………………. | Date: ……………………………. | Date: ……………………………. |