**Sponsor to Chief Investigator Sponsorship Agreement (Interventional Studies)**

**Including Conditions of Sponsorship and Delegation of Duties**

**Study Title**:

**IRAS Number:**

**Chief Investigator**:

**Bart’s Health NHS Trust [Barts Health]** will act as a Sponsor, as defined by theUK Policy Framework for Health and Social Care Research (2017) and all applicable UK regulation as and laws.

The Director of Research Services and Business development is delegated by Barts Health to act as sponsor representative on behalf of the organisation. The Joint Research Management Office (JRMO) Governance team is responsible for conduct of sponsor responsibilities except where delegated to the Chief Investigator (CI) and team.

Sponsorship of this study is granted on the condition that the CI adheres to the conditions described below. Failure to comply with any of these conditions will be escalated, where appropriate, and non-compliance may lead to study suspension and/or withdrawal of sponsorship.

The CI and all members of the research team must comply with all current regulations applicable to the performance of the study, including, but not limited to, the UK Policy Framework for Health and Social Care Research (2017), the World Medical Association Declaration of Helsinki (1996), and subsequent amendments, Good Clinical Practice Guidelines, the Human Tissue Act, GDPR and the Data Protection Act 2018.

Any requests from the sponsor for further information on the study are to be responded to promptly by the CI or delegated point of contact.

Sponsorship will not be activated, and therefore the study must not start, until: -

1. The Sponsor to CI Sponsorship Agreement has been signed by the CI and the sponsor’s representative.
2. Study has been registered and reported on a public database (clinicaltrials.gov/ISRCTN for the first 4 IRAS categories, including MHRA regulated studies)
3. CI has read and understood SOP 12a
4. CI to ensure that all recruitment for their studies is uploaded to EDGE in a timely manner and a POC (point of contact) has been provided to the JRMO team.
5. CI and co-ordinating team have previously attended an appropriate JRMO led Good Clinical Practice (GCP) training course. An appropriate external course is acceptable however, a JRMO refresher will be required
6. A “Favourable ethical opinion” from an appropriately constituted research ethics committee (REC) has been granted, received by the sponsor and, where applicable, ‘the conditions of favourable opinion’ have been met and sent to REC.
7. A Health Research Authority (HRA) approval letter has been issued and received by the sponsor.
8. Confidentiality Advisory Group (CAG) approval letter has been issued and received by the sponsor. (if applicable)
9. On an individual site basis, “Confirmation of Capacity and Capability” has been obtained from research sites.
10. Confirmation of Sponsorship and permission to activate sites has been obtained from the JRMO.

Additionally, during the study the CI must ensure that: -

1. Compliance
   1. The study is conducted in accordance with the protocol.
   2. All correspondence and communication with REC and other regulatory bodies is copied in full to the JRMO as sponsor.
   3. All amendments (including study extensions) are notified to and approval by the JRMO prior to submission to the REC or HRA. Once applicable approval is received, the CI must ensure that all sites are informed of the amendment and local approval/acknowledgment of each amendment is sought as appropriate.
   4. Participants give informed consent to participate in the study, using the process and documents that have received a favourable opinion by the REC. All e-consenting systems must be compliant with JRMO SOP 38a on Computer systems, fully validated and agreed by JRMO Governance team prior to use.
   5. The delegation log is always kept up to date and that the JRMO is notified of any major staff changes to the research team and the co-ordinating team.
   6. Appropriate contracts containing delegation of responsibilities are in place between third party sub-contractors and the sponsor before their work begins. The CI will notify the JRMO of all external parties, vendors or suppliers, and any changes in these.
   7. Sponsor approval is received for any additional Principal Investigator (PI), site or country selected to participate in the study, prior to formally involving them in the study.
   8. A Trial Master File (TMF) is created containing all essential documents appropriate for the study. This must be made available for monitoring, audit, or inspection as required.
   9. All non-compliances to protocol , GCP and relevant regulations are reported to the sponsor as per SOP 31 Non-Compliance.
2. Data Integrity
   1. All relevant clinical study data are transcribed from source documents (where applicable) to a case report form (CRF) and to a database. (For validation of database see SOP 38b Study Data Management Systems)
   2. All site CRFs are completed in full, and that they are signed and dated by the site PI or delegate.
   3. Sites are aware of their responsibilities to create and maintain accurate source data on all aspects of the study, this includes any electronic health data (e-HR). All site e-HR systems used to collect data must be appropriately validated.
   4. Data is generated, recorded, handled, stored, and reported accurately, securely and in accordance with the protocol, sponsor’s SOP 38b Study Data management Systems, GDPR and the Data Protection Act 2018 and GCP.
3. Reporting
   1. Written notice of any urgent safety measures taken to protect participants enrolled in the study are sent to the REC and sponsor within 3 days.
   2. If the study has CAG approval, then CAG APR’s are submitted to CAG within 30 days of the anniversary of CAG approval following review and approval by the JRMO.
   3. Any “sponsor oversight” documents which are requested are completed and returned in a prompt manner.
4. Safety
   1. Sites record all adverse events (AEs) in the patient’s notes (electronic or paper as appropriate) and CRF.
   2. Serious adverse events (SAEs) and unexpected serious adverse reactions relating to clinical studies of procedures or devices are reported to the sponsor (or delegate) within 24 hours of learning of the event.
   3. CI is the sponsor’s medical advisor for this study and is responsible for assessing every SAE and all the related issues on behalf of the sponsor. CI must ensure a delegated alternative medical advisor is clearly documented where CI cover is needed.
   4. CI is responsible for ensuring unexpected serious adverse reactions are reported to REC within the required timeframes.
   5. Potential serious breaches of GCP and the protocol are reported to the sponsor within 24 hours of the CI becoming aware of the breach.
5. Monitoring /Audits/Inspections
   1. All study documentation and staff involved in the study are available for monitoring/audit/inspection if requested by the sponsor.
   2. Monitoring arrangements outlined in the protocol, study SOP or manual and sponsor’s SOPs are complied with.
6. Study Closure
   1. The JRMO is notified of the end date of the study and any extension or early termination of the study, EDGE is also kept up to date with this information including current study status, study milestones etc.
   2. An “end of study notification” is sent to the REC within 90 days of the conclusion date, or within 15 days if the study is terminated early.
   3. Submit an end of clinical study report to the sponsor for review prior to final submission to REC within one year of the ‘end of study notification.
   4. Ensure all public databases are fully updated with the result in a timely manner
   5. TMF and all coordinating documents relating to the study are archived with the Trust’s Corporate Records archiving facility for a minimum of 25 years and in accordance with the JRMO archiving policy.
   6. All sites are adequately resourced to archive as per Sponsor’s SOP 20 (Archiving).
   7. The JRMO are notified of any outputs of the research such as guidelines, publications, presentation, changes in service delivery etc. prior to external submission or presentation. This includes declaration of any intellectual property stemming from the research.
   8. In the event that research misconduct or data integrity concerns have been raised, the JRMO, as sponsor, in discussion with senior management of the affected organisation, reserves the right to review, request a hold on publication submission or to refuse permission to publish.
7. Funding
   1. The CI must ensure all elements of the study are adequately funded, including ensuring adequate staffing and site costs. Any shortfall or overspend is the responsibility of the CIs Department or Institute. This applies to any subsequent amendments and extension to the study.

**Delegation of Duties**

**JRMO acting as Sponsor on behalf of Barts Health, delegates the responsibilities below to the CI.**

*This table will be reviewed and finalised on a per Study basis, this is a template, and the below table has been completed as a guide only.*

*Once table completely remove this highlighted text.*

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| **DUTIES** | **CHIEF INVESTIGATOR** | **SPONSOR** |
| Obtaining regulatory approvals following review and approval by the JRMO governance team | X |  |
| All interactions and consultation with the REC and HRA following consultation with the JRMO Governance team. | X |  |
| Requesting and maintaining regulatory approvals | X |  |
| Requesting and maintaining sponsor approval during the life cycle of the study | X |  |
| Creating and submitting all amendments following review and approval by JRMO governance team | X |  |
| Country, site, and Principal Investigator selection. | X | Sponsor retains the right to veto any country, site, or PI. |
| Generating study-specific risk assessment as per SOP 23 (Risk assessment) |  | X |
| Providing insurance / indemnity for study |  | X |
| Creating and submitting CAG APRs to REC, sponsor and distributing to sites, within 30 days of end of the reporting period following review by sponsor | X |  |
| Creating the end of study (EOT) notifications within 90 days of the end of study definition, or within 15 day if early termination occurs. Submitting EOT notifications following review by sponsor and keeping EDGE up to date with the latest study status including study milestone dates. | X |  |
| Creating and submitting the clinical study report within one year of end of study notification, following review by sponsor. | X |  |
| Compliance |  |  |
| Reporting and follow up of all suspected potential serious breaches of GCP and / or the protocol to Sponsor within 24 hours of becoming aware of the breach. This should include management of issues in liaison with sponsor ensuring corrective and preventive action (CAPA) is conducted in full. | X |  |
| Ensuring that all study activities are conducted within the remit of the patient consent provided. | X |  |
| Ensuring that all participants give full informed consent in writing. | X |  |
| Ensuring appropriate study standard operating procedures (SOPs) are produced and followed and the relevant sponsor’s SOPs are complied with. | X |  |
| Provide relevant information for sponsor oversight | X |  |
| Ensuring that PIs are informed of the requirement to re-consent, when appropriate. | X |  |
| Resolving clinical queries from participating sites / National Coordinating Centres | X |  |
| Performing monitoring as per protocol or monitoring plan | X |  |
| Ensuring compliance with any conditions within any contracts associated with the study. | X |  |
| Medical Advisor |  |  |
| Undertaking medical review of all serious adverse events, including their severity, causality, relatedness, and expectedness. | X |  |
| Study Documentation |  |  |
| Establishing and maintaining the study master file (TMF) following sponsor SOP 45 TMF where possible. | X |  |
| Generating and updating study documentation for the duration of the study (i.e. study protocol, patient documents etc.). | X |  |
| Ensuring document control procedures are in place and maintained for the duration of the study, including version control logs of all regulatory approved documents. | X |  |
| Creating, distributing, and implementing study-specific SOPs | X |  |
| Preparing and distributing Investigator Site File/s and study documents to participating sites. | X |  |
| Tracking and managing patient recruitment / randomisation, ensuring site and central enrolment log is up to date. | X |  |
| Ensuring all study management documents relating to the study are archived with the Trust’s Corporate Records archiving facility for a minimum of 25 years. | X |  |
| Ensuring all site documents are archived at all sites for a minimum of 25 years. | X |  |
| Study Committees |  |  |
| Setting up (including creation of committee terms of reference or charter), planning and coordination of study committees (including Study Management Groups, Study Steering Committees and Data Monitoring Committees as appropriate) and ensuring committees meet in accordance with study protocol. | X |  |
| Samples |  |  |
| Managing the collection, storage, and processing of samples. | X |  |
| Overseeing sample analysis and reporting. Ensuring appropriate documented procedures and quality control checks are in place | X |  |
| Ensuring appropriate disposal or transfer of samples prior to the end of the study notification. This should be conducted as per protocol and participant consent. | X |  |
| Pharmacovigilance |  |  |
| Ensuring systems are in place to allow expedited reporting of SAE reports from participating sites to CI within 24 hours of learning of the event. | X |  |
| Ensuring expedited reporting of unexpected serious adverse reactions to REC within and outside UK. | X |  |
| Data |  |  |
| Design and creation of case report forms (CRFs), ensuring their compliance to the protocol and regulatory application. | X |  |
| Final review and sign-off of CRFs | X |  |
| Database design, validation, and maintenance. | X |  |
| Final approval and sign-off of database | X |  |
| Data capture, integrity, and management (including data cleaning, issuing of queries, and resolving of data queries). | X |  |
| Ensuring that all generated data is recorded, handled, stored, and reported accurately, securely and in accordance with the protocol, GDPR and the Data Protection Act 2018 and GCP. | X |  |
| Registration and reporting of study on public database | X |  |
| Ensure EDGE records including study status, study milestones are up to date. | X |  |
| Ensuring database lock occurs prior to any analysis. | X |  |
| Statistical analysis. | X |  |

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| **Study title:** | | IRAS Number: |
| Chief Investigator:  **I have read and understood the above conditions and delegated duties and agree to adhere to these responsibilities and duties for the Study stated above.**  Name and Signature: Date: | | |
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| On Behalf of Sponsor:  **I have reviewed, discussed, and agree the delegation of duties outlined in this agreement.**  Name and Signature: Date: | | |