

# Declaration by Chief Investigator

I, ……………………………... , as Chief Investigator for

**Project Title: ………………………………………………………….**

**IRAS Number: ………………………………………………………..**

confirm that:

1. I understand the duties required of the Investigators, the Funders, and the Sponsor by the Research Governance Framework and appropriate legislation, and I am appropriately trained and qualified to undertake the duties of Chief Investigator.
2. I undertake to comply with the University’s research policies and procedures, research quality management system (SOPs), and, where applicable, the relevant legislation to the territory in which the research will be conducted.
3. I confirm that where I wish to delegate duties for carrying out specific functions to another member of the Study team, that individual will be appropriately qualified for the delegated function, will receive sufficient support and training to fulfil that function, and all delegated functions will be detailed e.g., in a Delegation Log.
4. I take full responsibility for the conduct and delivery of the research as proposed. I will ensure that a favourable ethical opinion from the HRA and research site approvals are obtained prior to the start of any research activity.
5. I shall conform to the requirements for reports to the Research Ethics Committee and requirements for reporting of any adverse events as detailed in [SOP11 Protocol deviations Violations and AE Reporting](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/DRAFT%20READY%20FOR%20REVIEW/SOP11%20Protocol%20deviations%20Violations%20and%20AE%20Reporting.docx).
6. I understand and agree that the study files, records data, and documents may be subject to review as part of an audit, inspection, or for monitoring purposes. I shall assist with audits, monitoring activity, and inspections of the conduct of the Study whether undertaken by the Sponsor or a regulatory body.
7. I understand that information relating to this research, and about me as a researcher, will be held by the R&I Directorate and on the Research Governance Database. This information will be managed according to the principles established in the UK’s Data Protection Act 2018.

Declaration: I accept: -

1. those functions delegated to me in the table contained in Schedule A; and
2. the general responsibilities set out above and the specific responsibilities and duties allocated to me in Schedule A

Signed by the **CHIEF INVESTIGATOR**

Signature: ……………………………………..

Name: ……………………………………..

Title: ……………………………………..

Date: ……………………………………..

Signed on behalf of **Manchester Metropolitan University**

Signature: ……………………………………..

Name: ……………………………………..

Title: ……………………………………..

Date: ……………………………………..

**Schedule A**

|  |  |  |
| --- | --- | --- |
| **Study responsibilities** | **Sponsor duty delegated/assigned to Chief Investigator** | **Clarification of split duties** |
| **A. Authorisation for clinical trials and research ethics committee opinion** | | |
| Develop study documentation e.g. Protocol, ICF, PIS, Risk Assessment. | Yes |  |
| Obtain favourable Research Ethics Committee Opinion | Yes | An authorised signatory from the R&I Directorate will sign as Sponsor Representative. |
| Obtain other appropriate approvals (e.g. GP practice approval, ARSAC, IRMER, HRA) | Yes | An authorised signatory from the R&I Directorate will sign as Sponsor Representative where required. |
| Obtain R&D Management Approval at all sites | Yes | R&I Directorate to implement Clinical Trial Site Agreements if appropriate. |
| Register Study with appropriate database (e.g. ISRCTN or clinicaltrials.gov) | Yes |  |
| Ensure that required contracts and agreements are in place and that the terms and conditions of the contracts and agreements are adhered to. | Yes |  |
| Keep records of all amendments to the authorisations and obtain approval where approvals are required | Yes | R&I Directorate to sign as Sponsor Representative and to monitor approvals – CI to ensure approvals are sent to RGT. |
| Ensure study site personnel are aware of dates of approval and implementation of amendments | Yes |  |
| Ensure annual progress reports are submitted to all relevant bodies (e.g. REC). | Yes | CI to copy R&I Directorate in to relevant correspondence. |
| Notify all relevant bodies of the conclusion or termination of the trial within the specified timeframes | Yes | CI to copy R&I Directorate in to relevant correspondence. |
| Ensure there are adequate insurance/indemnity arrangements cover provided to compensate any harm as a result of the study | Yes | Insurance cover will be confirmed by the Insurance Office via the Manchester Met Research Ethics procedure. |
| **B. GCP and the conduct of clinical trials** | | |
| Ensure that requirements for Good Clinical Practice training of study staff are met (where applicable) | Yes |  |
| Ensure that the conditions and principles of Good Clinical Practice and the Manchester Met quality management system are satisfied or adhered to | Yes | R&I Directorate to continue/withdraw sponsorship as required. |
| Oversight of internal functions | Yes |  |
| Oversight of external vendors | Yes |  |
| Oversight of investigator sites | Yes |  |
| Ensure that the trial is conducted in accordance with the protocol and subsequent amendments | Yes |  |
| Ensure that relevant study-specific quality control documents are prepared and available upon request and that these are adhered to | Yes |  |
| Notify any serious breaches of Good Clinical Practice or the protocol, or any urgent safety measures taken to the appropriate authorities/bodies | Yes | To be notified as per [SOP11 Protocol deviations Violations and AE Reporting](http://www2.mmu.ac.uk/media/mmuacuk/content/documents/research/DRAFT%20READY%20FOR%20REVIEW/SOP11%20Protocol%20deviations%20Violations%20and%20AE%20Reporting.docx) |
| Ensure study products and relevant devices are available to subjects free of charge | Yes |  |
| Ensure that the study data is of high-quality, accurate and held/processed securely and confidentially. | Yes |  |
| Keep a study master file to hold all documents relating to that trial | Yes |  |
| Ensure site files are maintained at each participating site | Yes |  |
| Obtain written informed consent and ensure consent forms are retained in appropriate site files. | Yes |  |
| Appoint named individuals responsible for archiving the trial essential documents | Yes |  |
| **C. Participant Safety** | | |
| Keep records of all adverse events relating to that trial which are reported by investigators | Yes |  |