**CHIEF INVESTIGATOR DECLARATION**

# Declaration by Chief Investigator

I, (**Name)**……………………………………………, as Chief Investigator for

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

**ERN Reference:** ………………………………………**Sponsored by University of Birmingham,**

confirm that:

1. I understand the duties required of the Investigators, the Funders and the Sponsor by the UK Policy Framework for Health and Social Care Research 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 policies and procedures and the principles of the UK Policy Framework for Health and Social Care Research or equivalent in the devolved nations, the principles of Good Clinical Practice, the Protocol, the University of Birmingham’s Clinical Trial Management SOP portfolio (<http://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx>) 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 after obtaining favourable REC review and any appropriate Site Research & Development permissions, and, where applicable, authorisation from the relevant competent authority (for the UK this is the Medicines and Healthcare products Regulatory Agency).
5. I shall conform to the requirements for annual reports to the Competent Authority and/or Research Ethics Committee and requirements for reporting of any Urgent Safety Measures, Serious Breaches and Suspected Unexpected Serious Adverse Events as described the UK legislation and in any event shall notify the Sponsor forthwith upon receiving notification of such an event, following the University’s Clinical Trial SOP portfolio.
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 Research Governance Team and on the Research Governance Database. This information will be managed according to the principles established in the Data Protection Act 2018.
8. I confirm that I have completed the On-line Registration form and lodged details of my research databases/datasets with the information Compliance Manager in accordance with the University’s Data protection Policy: <https://intranet.birmingham.ac.uk/legal-services/Data-Protection/Data-Protection.aspx>

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: ……………………………………..……………………………………..

**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 MHRA Clinical Trials Authorisation (CTA) | Yes | The Research Governance Team will sign as Sponsor Representative. |
| Obtain favourable Research Ethics Committee Opinion | Yes | The Research Governance Team will sign as Sponsor Representative. |
| Obtain other appropriate approvals (e.g. GP practice approval, ARSAC, IRMER) | Yes | The Research Governance Team will sign as Sponsor Representative where required. |
| Obtain R&D Management Approval at all sites | Yes | Research Governance Team to implement Clinical Trial Site Agreements |
| 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 | Contracts Office to draft agreements, and CI to ensure agreements are adhered to.  |
| Keep records of all amendments to the authorisations and obtain approval where approvals are required | Yes | Research Governance Team to sign as Sponsor Representative and to monitor approvals – CI to ensure approvals are sent to RGT.  |
| Produce undertaking to allow inspection of premises in third countries if required | Yes | Contracts Office to ensure contracts/agreements reflect this.  |
| 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. APR and DSUR to REC and MHRA). | Yes | CI to copy Research Governance Team in to relevant correspondence. |
| Notify all relevant bodies of the conclusion or termination of the trial within the specified timeframes | Yes | CI to copy Research Governance Team in to relevant correspondence. |
| Ensure there are adequate insurance/indemnity arrangements cover provided to compensate any harm as a result of the study  | Yes | As per University of Birmingham Clinical Trial Management Standard Operating Procedure, Research Governance Team will arrange and confirm insurance cover  |
| **B. GCP and the conduct of clinical trials** |
| Ensure that requirements for GCP training of study staff are met | Yes |  |
| Ensure that the conditions and principles of Good Clinical Practice and the UoB quality management system are satisfied or adhered to  | Yes | Clinical Research Compliance Team to:* Develop/maintain the University of Birmingham Clinical Trials Quality Management System to be adhered to by CI/UKCRN registered Clinical Trials Units and other University of Birmingham stakeholders involved in clinical trials
* Perform and report on sponsor support visits and audits (University of Birmingham sponsored trials, University of Birmingham Clinical Trials Units) and report major issues to Clinical Trials Oversight Committee

Clinical Trials Oversight Committee to advise on continuation of sponsorshipResearch Governance Team 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  | Yes | As per University of Birmingham Clinical Trial Management Standard Operating Procedure, Serious Breaches must be reported to the Clinical Research Compliance Team for review. The Clinical Research Compliance Team to feedback major issues to CTOC. In addition, Clinical Research Compliance Team to work together with CI/UKCRN registered Clinical Trials Unit to ensure Corrective Action and Preventative Action is appropriate, and Clinical Research Compliance Team to ensure the University of Birmingham Clinical Trials Quality Management System is amended where needed to avoid recurrence.  |
| Ensure investigational medicinal products and relevant devices are available to subjects free of charge | Yes | Contracts Office to ensure contracts/agreements reflect this. |
| Ensure that the study data is of high-quality, accurate and held/processed securely and confidentialy. | Yes |  |
| Keep a trial master file to hold all documents relating to that trial | Yes | RGT will hold a Sponsor file to allow for Sponsor oversight. |
| 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. Pharmacovigilance** |
| Ensure an investigator’s brochure exists and is validated and updated at least annually | Yes |  |
| Devise and implement urgent safety measures | Yes |  |
| Keep records of all adverse events relating to that trial which are reported by investigators | Yes |  |
| Recording and reporting suspected unexpected serious adverse reactions to appropriate authorities within specified timelines | Yes |  |
| Ensure investigators are informed of suspected unexpected serious adverse reactions | Yes | Research Governance Team will inform CI/UKCRN registered Clinical Trials Units managing University of Birmingham sponsored trials of other University of Birmingham sponsored trials using the same IMP. |
| Ensure all suspected unexpected serious adverse reactions including those in third countries are entered into the European database | Yes |  |
| Provide annual list of suspected serious adverse reactions and a safety report to the appropriate authorities | Yes |  |
| **D. Manufacture and labelling of investigational medicinal products** |
| Meet requirements for the authorisation to manufacture and import investigational medicinal product (including the use of hospital exemptions) | Yes |  |
| Ensure Certification of the investigational medicinal product by a Qualified Person | Yes |  |
| Follow two-step release process of investigational medicinal product (‘technical release’ and ‘regulatory release’) | Yes |  |
| Obtain Regulatory green light approval | Yes |  |
| Ensure investigational medicinal product is labelled in accordance with Article 15 of Commission Directive 2003/94/EC | Yes |  |
| Maintain oversight of IMP activities at investigator sites | Yes |  |