# Declaration by Chief Investigator

*[Student research - Supervisors or course leaders should be the Chief Investigator for student health and social care research, including those at PhD and doctoral level. This is because the CI responsibility includes ensuring the research is scientifically sound, all relevant approvals are in place, satisfying themselves everyone is qualified to fulfil their roles as described in the UK Policy Framework. Exception is made for an experienced care practitioner or manager undertaking an educational qualification for continuing professional development or doctoral-level study whilst employed by a health or social care provider or a LJMU, or for a researcher undertaking a doctoral-level study in receipt of a fellowship.]*

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

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

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 LJMU’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 (LJMU REC or NHS REC as appropriate) 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.
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 LJMU REG.

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 favourable Research Ethics Committee Opinion | Yes | An authorised signatory from LJMU REG will sign as Sponsor Representative. |
| Obtain other appropriate approvals (e.g. GP practice approval, ARSAC, IRMER) | Yes | An authorised signatory from LJMU REG will sign as Sponsor Representative where required. |
| Obtain R&D Management Approval at all sites | Yes | LJMU REG 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 |  |
| Keep records of all amendments to the authorisations and obtain approval where approvals are required | Yes | LJMU REG to sign as Sponsor Representative and to monitor approvals – CI to ensure approvals are sent to LJMU REG.  |
| 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 LJMU REG in to relevant correspondence. |
| Notify all relevant bodies of the conclusion or termination of the trial within the specified timeframes | Yes | CI to copy RKE Office in to relevant correspondence. |
| Ensure there are adequate insurance/indemnity arrangements cover provided to compensate any harm as a result of the study  | Yes |  |
| Ensure that requirements for GCP training of study staff are met (where applicable) | Yes |  |
| Ensure that the conditions and principles of Good Clinical Practice and LJMU quality management systems are satisfied or adhered to  | Yes | LJMU REG to continue/withdraw sponsorship as required. |
| Oversight of internal functions  | Yes |  |
| Oversight of external vendors if applicable | 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 |   |
| Ensure study products and relevant devices are available to participants 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 study | Yes |  |
| Ensure site files are maintained at each participating site | Yes |  |
| Obtain informed consent and ensure consent forms are retained in appropriate site files. | Yes |  |
| Appoint named individuals responsible for archiving the study essential documents | Yes |  |
| Keep records of all adverse events relating to that study which are reported by investigators | Yes |  |