

## Roles & Responsibilities of Chief Investigator Agreement

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| <b>Study Title (in full):</b> |  |
| <b>Reference No:</b>          |  |

**The Chief Investigator (CI) and all members of the research team shall comply with all current regulations (as amended from time to time) applicable to the performance of the study including, but not limited to:**

- Policy Framework for Health & Social Care or relevant Governance Framework
- The Principles of the World Medical Association Declaration of Helsinki
- Data Protection Act (1998/2018)
- General Data Protection Regulations (2018)
- ICH Good Clinical Practice Guidelines (1996) and Revision 2 (R2 2017)
- Human Tissue Act (2006)
- UK Medicines for Human Use (Clinical Trials) Regulations (2004)
- UK Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, SI 2006/1928
- The UK Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006, SI 2006/2984
- The Medicines for Human Use (Clinical Trials) and Blood Safety and Quality (Amendment) Regulations 2008, SI 2008/941
- The Mental Capacity Act (2005)

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| I confirm that I have read and understood my responsibilities as listed above | CI Initials: |  |
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**The CI must not permit the study to commence at any site until a formal confirmation of Sponsor ‘Green Light’ has been received.**

UoL Sponsor ‘Green Light’ will be confirmed in writing when the following checks as appropriate to the nature of the study have been verified and evidence received by the Sponsor:

- Appropriate Ethics Committee Favourable Opinion – either through NRES (NHS Ethics System) or via a University Ethics Committee
- Copies of all documentation listed on the Favourable Opinion letter issued by an Ethics Committee
- Evidence of appropriate feasibility assessment for each site
- Evidence of HRA approval
- The local package must be submitted by the CI (or delegate) to each R&D/R&I department and/or local study delivery team at each participating site
- Confirmation of capacity and capability from each R&D / R&I office at each participating site
- Monitoring arrangements have been discussed, and confirmed through the UoL Research Governance Manager as appropriate (where required)
- Confirmation or ‘notice of acceptance letter’ has been received from the Medicines and Healthcare products Regulatory Agency as appropriate for Medicinal Products or Devices research
- Evidence of appropriate permission to access NHS resources for each member of the research team has been received e.g. where a Substantive or Honorary Contract is not held with the NHS Trust, Letters of Access or Honorary Research Contracts have been obtained
- The study is adequately resourced and has been signed off by the R&D finance lead
- Evidence that all support departments have agreed in writing to provide services required
- All other relevant permissions have been obtained
- Confirmation that the protocol has undergone appropriate scientific and statistical review, and is compliant with the relevant regulations / guidelines

I confirm that I have read and understood my responsibilities as listed above

CI Initials:

**During the study it is the CI responsibility to ensure that:**

- The study is conducted in accordance with the approved version of the protocol and subsequent amendments
- Delegation of any responsibilities are clearly documented on the Delegation of Authority and Signature Log before study activity commences, and the Sponsor kept informed of personnel changes
- All participants are consented using the correct version of the consent form as well as using the process agreed and documented in the application
- Access by UoL Sponsor representatives to all consent forms is facilitated where necessary to perform audits during the course of the study
- Reporting of Urgent Safety Measures (USM) and subsequent management in line with Regulatory requirements
- Amendments are submitted to the Sponsor prior to submission to the relevant authorities i.e. MHRA, REC / HRA. Evidence of approval must be provided to the Sponsor prior to their implementation – unless in emergency circumstances (USM) where retrospective approval is acceptable
- The Investigator Brochure (IB) or (SPC) is reviewed and where appropriate updated annually and recorded in the TMF
- A Trial Master File (TMF) is created, including individual sections for additional sites where required
- All relevant Standard Operating Procedures and policies have been made available to research team and a ‘read record’ retained in the study team training file
- Annual progress on the anniversary of the Ethics Favourable Opinion and where relevant, Development Safety Update Reports (DSUR) on the anniversary of the Clinical Trials Authorisation are produced and sent to the Sponsor prior to submission to relevant agencies
- All communication to the MHRA, REC and other regulatory bodies are copied to the Sponsor representative for authorisation and processing where relevant
- Quality control systems for data handling are in place and all data stored on computers which are not part of the local network are adequately encrypted and secure
- Quality control systems for the validation of data when using ‘self-built’ software programmes rather than preparatory software are in place. In cases of CTiMP studies, the Investigator Brochure (IB) or Summary of Product Characteristics (SmPC) is updated or reviewed on an annual basis, and is documented in TMF
- The Reference Safety Information (RSI) is updated as appropriate and approved by the MHRA by substantial amendment if necessary
- Study is registered as appropriate on a relevant Protocol Registration Scheme e.g., ClinicalTrials.gov
- The terms of any data sharing agreement (e.g. with HSCIC) are agreed with
- A Statistical Analysis Plan is in place prior to database lock if applicable
- Act as the ‘Data Controller’ as delegated by the Sponsor on a study by study basis

I confirm that I have read and understood my responsibilities as listed above

CI Initials:

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**At the end of the study, the CI must ensure that:**

- End of study notification is completed and sent to the Sponsor for review and processing
- Documents relating to the study are archived in accordance with the Archiving SOP
- The Sponsor is notified of any outputs, publications or changes in service as a result of the study

I confirm that I have read and understood my responsibilities as listed above

CI Initials:

**For Multi-site studies ONLY. It is the Chief Investigator's responsibility to ensure that:**

- The Sponsor is consulted **BEFORE** applications to expand the study into additional sites is made
- Feasibility is received from each participating site
- All documentation relating to the application to additional sites is copied to the Sponsor
- The local package is submitted to each R&D/R&I department and/or local study delivery team at each participating site
- Ensure that no recruitment related activity commences at any site prior to the Sponsor Green Light confirmation being received for that site
- All research staff at additional sites are appropriately trained in ICH GCP and consent in accordance with Sponsor requirements
- All members of the Site Study Team are able by knowledge, training and experience to undertake the roles they accept
- An Investigator Site File containing the essential documents is maintained and inspection ready at each site
- All Sponsor SOPs, are adhered to in addition to the SOPs of the participating centre if different
- Assist with investigations into any alleged research misconduct undertaken by or on behalf of the Sponsor
- Make necessary provision for archiving of essential documents

I confirm that I have read and understood my responsibilities as listed above

CI Initials:

**Chief Investigator Declaration**

**I have read the above and agree to adhere to these responsibilities for the study stated above.**

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| <b>Chief Investigator:</b> |  | <b>Sponsor Representative:</b> |  |
| <b>Signature:</b>          |  | <b>Signature:</b>              |  |
| <b>Date:</b>               |  | <b>Date:</b>                   |  |