**Roles & Responsibilities of Chief Investigator Agreement**

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| **Study Title (in full):** |  |
| **Reference No:** |  |

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| **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 project, including, but not limited to:** | | |
| NHS Research Governance Framework for Health and Social Care (Version 2 April 2005)  The Principles of the World Medical Association Declaration of Helsinki  Data Protection Act (1998)  ICH Good Clinical Practice Guidelines (1996)  Human Tissue Act (2004)  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) | | |
| 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 project to commence at any site until a formal letter confirming Sponsor Approval has been received.**  LU Sponsor Approval 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 through NRES (NHS Ethics System)  Copies of all documentation listed on the Favourable Opinion letter issued by an Ethics Committee  Confirmation that all appropriate Research Management and Governance checks have been completed and approved for each site  Monitoring arrangements have been discussed, and confirmed through the LU Research Governance Officer 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 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: |  |

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| **During the project it is the CI responsibility to ensure that:** |
| The project 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 commenced, 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 LU Research Office staff to all consent forms is facilitated where necessary to perform audits during the course of the study  Amendments are submitted to the Sponsor prior to submission to the relevant authorities i.e. REC. Evidence of approval must be provided to the Sponsor prior to their implementation – unless in emergency circumstances, where retrospective approval is acceptable  Reporting of Urgent Safety Measures and subsequent management in line with Regulatory requirements  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 are produced and sent to the Sponsor prior to submission to relevant agencies  All communication to the 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 the case of studies deemed to be of higher risk, an annual meeting between study staff and Sponsor is facilitated  Study is registered as appropriate on a relevant Protocol Registration Scheme |
| CI Initials: |

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| **At the end of the project, the CI must ensure that:** |
| End of trial notification is completed and sent to the Sponsor for review and processing  Documents relating to the project are archived in accordance with the Archiving policy  The Sponsor is notified of any outputs, publications or changes in service as a result of the project |
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| **For Multi-site studies ONLY. It is the Chief Investigator responsibility to ensure that:** |
| The Sponsor is consulted **BEFORE** applications to expand the study into additional sites is made  All documentation relating to the application to additional sites is copied to the Sponsor  Ensure that no recruitment related activity commences at any site prior to the Sponsor Approval confirmation being received for that site  Provision of monitoring for the project is discussed prior to any applications for the expansion of the study to additional sites are made  All research staff at additional sites are appropriately trained 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 |
| CI Initials: |

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| **Chief Investigator Declaration** | | | |
| **I have read the above and agree to adhere to these responsibilities for the project stated above.** | | | |
| **Chief Investigator:** |  | **Sponsor Representative:** |  |
| **Signature:** |  | **Signature:** |  |
| **Date:** |  | **Date:** |  |