LOUGHBOROUGH UNIVERSITY RESEARCH OFFICE
STANDARD OPERATING PROCEDURE

Loughborough University (LU) Research Office
SOP–1010 LU

Chief Investigator Responsibilities for NHS Research Sponsored by Loughborough University

Effective Date: October 2015

1.0 Introduction

This Standard Operating Procedure (SOP) describes the role and responsibilities of the Chief Investigator for research sponsored by Loughborough University (LU).

The outcome is that the Chief Investigator (CI) is aware of and has agreed to all roles and responsibilities as delegated to them by the Sponsor prior to the commencement of the research.

A senior individual must be designated as the CI for any research undertaken in or through the NHS or social services or using participants' organs, tissue or data. The CI is the person designated to take overall responsibility within the team of researchers for the design, conduct and reporting of the study.

The CI must ensure that the study is planned, set-up, conducted, documented and reported according to the protocol, relevant Standard Operating Procedures (SOPs), International Conference on Harmonisation Good Clinical Practice (ICH-GCP) and appropriate regulatory requirements.

In the case of a single site study, a CI may also be the Principal Investigator (PI). In these cases, the roles & responsibilities of the CI will over ride those of a PI.

2.0 Scope

This SOP applies to ALL Chief Investigators of studies sponsored by LU.

3.0 Procedure

The CI must be a senior individual, with appropriate experience, expertise and training to undertake the design, conduct and analyses of the study to the standards set out in the legislation. They must also lead and manage others who have been delegated responsibilities in the research.
The CI must initial on each page, and sign at the end of the Role & Responsibilities of the CI document during the Sponsor review process. Completion of this document forms part of the Sponsor approval confirmation.

The CI has overall responsibility for the conduct of the research and is accountable to their employer, the Sponsor, when different, and the host organisation where the research takes place. If the research is taking place at more than one site, the Chief Investigator takes on personal responsibility for the design, management and reporting of the study, and coordinating the personnel at the other sites.

The CI is responsible for ensuring that:

- The research team gives priority at all times to the dignity, rights, safety and wellbeing of the participants.
- They understand the legal and ethical requirements in research, and are familiar with the appropriate standard operating procedures and policies relating to research.
- The study complies with all legal and ethical requirements.
- The research is conducted to the standards as set out in the Research Governance Framework.
- Each member of the research team, including those at collaborating sites, is qualified by education, training and experience to discharge their role in the study, and their qualifications are documented and retained in the Investigator Site File.
- Students and new researchers have adequate supervision, support and training.
- A suitable sponsor is secured and agreements are in place detailing the responsibilities of all parties involved in the research.
- Trust (R&D) Approval is obtained from each care organisation and subsequent Sponsor Approval received prior to commencing the study at each care centre.
- The protocol is submitted for sponsor review and agreement prior to submitting for ethics review.
- The study does not start without a favourable opinion from a Research Ethics Committee, Trust (R&D) approval and where relevant competent authority approval and Sponsor Approval.
- The research team acts on any conditions attached to the ethics opinion.
- Unless urgent safety measures are necessary, the research follows the protocol or proposal agreed by the relevant ethics committee, by the Trust R&D Office and by the Sponsor.
- Substantive changes to the protocol are submitted for Sponsor approval prior to ethical, regulatory and Trust approval before implementation, with the exception of urgent safety measures.
- Each member of the research team, who has direct involvement with participants and/or identifiable data, has a full or honorary contract or research passport.

- When a study involves participants under the care of another clinician, they are informed of their participation.
- When the research involves a service user, or carer or a child looked after or receiving services under the auspices of the local authority, the agency director or their deputy agrees to the person being invited to participate, and is fully aware of the arrangements for dealing with any disclosures or other relevant information.
- Potential participants and other service users and carers are involved in the design and management of the study whenever appropriate.
- Report Serious Adverse Events to the Sponsor, R&D, Research Ethics Committee & the competent authority as required
- Procedures are in place to ensure collection of high quality, accurate data and to maintain the integrity and confidentiality of data during processing and storage.
- Arrangements are in place for the management of any intellectual property arising from the research.
- The CI should submit annual written summaries of the trial status to the Sponsor, Trust R&D Office, NHS Ethics Committee and the Competent Authority and provide a summary outcome at the end of the trial. This includes annual / end of trial safety reporting.
- Once established, findings from the work are disseminated promptly and fed back as appropriate to participants.
- There are appropriate arrangements to archive the data when the research has finished, and to ensure it is still accessible.
- All data and documentation relating to the trial are available at the request of the inspection and auditing authorities.
- Where the CI delegates responsibilities to members of the research team, this must be clearly documented in a delegation of authority and signature log (template available through the Ethics Approvals (Human Participants) Sub-Committee website). The CI remains accountable for the actions of their research team.
- Complete and sign Roles and Responsibilities document prior to commencing any part of the research study.

3 Responsibilities

	Responsibility	Undertaken by	Activity
1	Sponsor	Research Governance Officer	Confirm roles and responsibilities document signed as part of the Sponsor Approval process
2	Sponsor	Research Governance Officer	Ensure Chief Investigator documents any delegated duties appropriately using the Delegation of Authority and signature log.
3	Chief Investigator	Chief Investigator	Ensures all roles and responsibilities are undertaken

4 Monitoring and Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead

All research sponsored by LU has appropriate contracts in place.	Included in the monitoring / audit programme.	Random audits / monitoring conducted on 10% of research activity.	Research Governance Officer or their Delegate

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Jackie Green	**Job Title:** Research Governance Officer
Approved by:	Ethics Committee	**Date Approved: 23/10/15**

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**

DISTRIBUTION RECORD:			
Date	**Name**	**Dept**	**Received**

Roles & Responsibilities of Chief Investigator Agreement

Study Title (in full):	
Reference No:	

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:	

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:	

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:

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
CI Initials:

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:

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:**	