Research & Innovation Office

Standard Operating Procedure

St Luke's Hospice

Investigator Responsibilities

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Related SOP's: Research Policies & procedures. V3. Dated 21/01/2025 SLHSOP001. Informed consent. V1 dated 23/06/2025 SLHSOP002. Archiving. V1 dated 23/06/2025 SLHSOP003. Documenting Source data. V1 dated 23/06/2026 SLHSOP004 – Maintaining a study site file. V1 dated 23/06/2025		**Document Summary:** Describes Research Investigator role and responsibilities.	
Approved by (name & Role)	Dr Paul Taylor Head of Research - SLH	**Date**	30/06/2025
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Acronyms

CI – Chief Investigator
PI- Principal Investigator
CTIMP - Clinical Trial of an Investigational Medicinal Product
SOP – Standard Operating Procedure
R&IO – Research & Innovation Office
SLH – St Luke's Hospice
TMF - Trial Master File
CRFs - Case Report Forms
ISF - Investigator Site File
SLH – St Luke's Hospice
CARG – Clinical Audit & Research Group

Introduction

The UK policy framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research that take account of legal requirements and other standards.

UK Policy Framework for Health and Social Care Research - Health Research Authority

The UK policy framework for health and social care research recommends that 'there is clear designation of responsibility and accountability with clear lines of communication between all those involved in research. Communication pathways should be clear in terms of what, how, who, when and why, with documented roles and responsibilities. Any documentation should be proportionate. Roles and responsibilities should be agreed and understood by all the relevant parties but are not expected to be re-documented separately if their description for the purpose of review processes such as research ethics committee review is sufficient).'

Purpose

This SOP relates to all Chief Investigators (CI), Principal Investigators (PI), Sub- PI, Associate PIs and Sub-Investigators of research hosted by St Luke's Hospice.

The purpose of this document is to provide more detailed overview of the responsibilities for research investigators. Investigators are ultimately responsible for the conduct of research. Investigators may delegate tasks to appropriately trained and qualified members of their research team; however, investigators must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibilities.

Roles and responsibilities

All SOPs can be accessed on the Hospice website.

The Research & Innovation Office is responsible for managing Hospice R&I SOPs including their approval, dissemination and archiving. All Hospice R&I SOPs are available and published on the Hospice website.

Role definitions

Chief Investigator (CI) is the overall lead researcher for a research project (Outside the UK the term Coordinating Investigator or Investigator may be used). In addition to their responsibilities if they are members of a research team, chief investigators are responsible for the overall conduct of a research project. The CI must be a senior individual, with appropriate experience, expertise, and training to undertake the design, conduct and analysis of the study to meet the requirements set out in legislation. (As defined by GCP guidance). They must also lead and manage others who have been delegated responsibilities as part of the research project.

Chief Investigators of Clinical Trials of an Investigational Medicinal Product (CTIMPs)

The Medicines & Healthcare products Regulatory Agency (MHRA) has produced guidance as to who can act as the Chief Investigator for Clinical Trials of Investigational Medicinal Products (CTIMPS) taking place in the UK. It includes a definition of the term '**Authorised Health Professional'** and examples of which professions this term applies to i.e. a Doctor, Dentist, Nurse or Pharmacist.

a) in relation to a clinical trial conducted at a single trial site, the investigator for that site, or

b) in relation to a clinical trial conducted at more than one trial site,
the authorised health professional, whether or not they are an investigator at any particular site, who takes primary responsibility for the conduct of the trial;

Principal Investigator (PI) is the person who takes responsibility for the initiation and conduct of the study at site. There is usually one Principal Investigator at each site participating in a research study. The Chief investigator may also take on the role of Principal Investigator.

Sub-PI is any individual other than the PI who is involved in the conduct of a research study and who with appropriate training and qualification may act on behalf of the PI when they are absent, their role should be clearly agreed and delegated with the sponsor and CI.

Associate PI is a healthcare professional who does not have research as a core part of their role, who is given the opportunity to experience what it means to work on and deliver a NIHR portfolio trial under the mentorship of a local PI.

Sub-Investigator is any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).

Specifics of this SOP

Responsibilities of individuals and organisations

There should be clear designation of responsibility and accountability with clear lines of communication between all those involved in research. Communication pathways should be clear in terms of what, how, who, when and why, with documented (Any documentation should be proportionate. Roles and responsibilities should be agreed and understood by all the relevant parties but are not expected to be re-documented separately if their description for the purpose of review processes such as research ethics committee review is sufficient) roles and responsibilities.

Dialogue and collaboration have a central role within a research project. Clear, upfront discussion of issues and agreement of principles and procedures for each project are essential to its effective conduct and success, as well as mitigating some risks. All individuals and organisations with responsibilities under this policy framework should understand the value of research to health and social care and recognise the importance of co-operation and shared endeavour as critical to its

success. Those with experience of good practice in the management and conduct of research are encouraged to share their knowledge with novices.

Role of the Chief Investigator (CI) for Hosted Studies

The responsibilities of the Chief Investigator (CI) may vary dependent upon whether the study is hosted or sponsored. The CI for the study may also be the Principal Investigator (PI) for the study hosted by St Luke's Hospice.

The CI for studies hosted by St Luke's Hospice is responsible for:

- Being aware of and agreeing to all roles and responsibilities as delegated to them by the sponsor prior to the commencement of the research.
- Understanding and applying the legal and ethical requirements in research and adhering to the appropriate standard operating procedures and policies relating to research.
- Ensuring that the study is planned, set-up, conducted, documented, and reported according to the protocol, relevant SOPs, International Conference on Harmonisation Good Clinical Practice (ICH-GCP) and appropriate regulatory requirements.
- Ensuring that the information given to potential participants is in a suitable format, clear and relevant to their participation in the research and, where consent is required, to their decision-making about taking part in the research (HRA decision tool).
- Adhering to the agreed arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after the research has finished (sponsors, funders or others may set expectations about making data and tissue available).
- Ensuring that everyone involved in the conduct of the research is qualified by education and/or training. Training should be appropriate and proportionate to the type of research being undertaken and should cover the responsibilities of researchers set out in relevant legislation and standards and experience, or

otherwise competent, to discharge their roles in the project – as detailed by the HRA (Research suitability and training). For multisite projects, this may be delegated to the principal investigator at each research site.

- Ensuring that arrangements are in place for the management of any intellectual property arising from the research.
- Adhering to the agreed procedures and arrangements for reporting (e.g., progress reports, safety reports) and for monitoring the research, including its conduct, the participants' safety and well-being, and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.
- Notifying the sponsor of any Serious Adverse Events (SAEs) which occur for all participants taking part in CTIMP studies. This immediate report may be made either orally or in writing, as long as a detailed written report follows the immediate report.
- Supporting in the assessment of all SAEs, Serious Adverse Reactions (SARs) and Suspected Unexpected Serious Adverse Reactions (SUSARs). (*Refer to Individual CTIMP SOP's for processing and reporting SAEs, SARs and SUSARs for details of the procedures*).
- Ensuring that the Trial Master File (TMF) is maintained and kept inspection ready at all times.
- Ensuring that all data and documentation relating to the study are available at the request of the inspection and regulatory authorities. The sponsor must be kept informed of the location of all archived data and the contact details of the person responsible.
- Submitting annual written summaries of the trial status to the Sponsor, Trust R and D Offices, St Luke's R&IO, 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.
- Ensuring that there are appropriate arrangements in place to archive the TMF/Investigator Site File (ISF) and anonymised data when the research has finished, and to ensure it is still accessible when required. Upon receiving

sponsor confirmation that the archiving period has expired; the CI must ensure that appropriate destruction of the TMF/ISF is undertaken in accordance with relevant St Luke's Hospice policies and procedures.

- The responsibilities outlined below, if also acting as the Principal Investigator for the site.

Role of the Principal Investigator (PI)

The Principal Investigator (PI) is responsible for the local site in a study and may also be the Chief Investigator for the study. The PI is responsible for ensuring:

- 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 UK Policy Framework for Health and Social Care Research.
- The Investigator Site File (ISF) is always maintained and kept inspection ready.
- Each member of the research team, is qualified, trained and has relevant experience to discharge their role within the study, and their qualifications are documented and retained in the ISF
- All delegated roles and responsibilities are appropriately recorded within the delegation log held in the Investigator Site File (ISF) for each study. The PI can delegate duties, but never the responsibility for the study at the site.
- The PI remains accountable for the actions of their research team, ensuring all eligibility assessments are met and participants consented, recruited and followed-up appropriately.
- All research staff involved in Clinical Trial of Investigational Medicinal Product (CTIMP) studies are aware of their legal responsibilities.
- Students and new researchers are adequately trained, supervised and supported.

- The study does not start without the relevant approvals from the MHRA (as appropriate), HRA, REC, ST Lukes R&IO capacity and capability confirmation and sponsor's Green Light (authorisation to begin recruitment).
- 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, sites R&D function and by the sponsor.
- Relevant approvals have been received for changes (amendments) to the protocol or study documentation prior to implementation, apart from Urgent Safety Measures.
- Each member of the research team, who has direct involvement with participants and/or identifiable data, has a contract of employment with the organisation, honorary contract or research passport.
- When applicable, the participant's GP is informed of their participation in a clinical study.
- Safety reporting including reporting Serious Adverse Events (SAEs), Serious Adverse Reactions (SARs) and Suspected Unexpected Serious Adverse Reactions (SUSARs) are communicated to the CI, sponsor and SLHR&IO as required. (*Refer to Individual CTIMP SOP's for processing and reporting SAEs, SARs and SUSARs for details of the procedures).*
- 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.
- Once published, 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 remains accessible.
- All data and documentation relating to the trial are available at the request of the inspection and auditing authorities.

- They are appropriately available for monitor meetings and ensure sponsor feedback is acted upon promptly.

Role of the Sub-Principal Investigator (PI)

The Sub-PI is any individual other than the PI who is involved in the conduct of a research study and who with appropriate training and qualification may act on behalf of the PI when they are absent. Their role should be clearly agreed and delegated with the sponsor and CI. The Sub-PI is responsible for:

- Undertaking part or all the PI's activities for a research study, as determined by the sponsor, protocol, and as delegated by the PI.
- Ensuring that they are adequately trained and familiar with the protocol, informed of any changes in the protocol and provided with safety information including the Investigators Brochure (IB) and all safety updates.

Role of the Associate Principal Investigator

The Associate PI can carry out delegated tasks under the supervision of the study PI, suitable to their clinical role.

Role of the Sub-Investigators (Sub-I)

The Sub-investigator (Sub-I) is responsible for:

- Undertaking part or all the PI's activities for a research study, as determined by the sponsor, protocol, and as delegated by the PI.
- Ensuring that they are adequately trained and familiar with the protocol, informed of any changes in the protocol and provided with safety information including the Investigators Brochure (IB) and all safety updates.

Research leadership at St Luke's

Clinical and non-clinical staff can act as a Chief or Principal Investigator. At St Luke's Hospice, in order to act as a CI it is expected that the individual will be a senior

academic with an established track record in research conduct or a senior and experienced member of the St Luke's team.

A clinical academic is someone who is qualified and trained in both medicine and science. Outside of Clinical Academic routes, registered professionals can gain relevant experience and training through academic fellowships, clinical training fellowships and in-practice fellowships.

To take on the role of PI at St Luke's Hospice, an individual requires the right training and experience to undertake the role for a specific study. This will be managed via the Clinical Audit & Research Group (CARG) at St Luke's Hospice; CARG will decide whether or not an individual has the requisite training and experience, and will seek guidance from the CRDC if required.

Students

Students should not normally (Exception is made for an experienced care practitioner or manager undertaking an educational qualification for continuing professional development or a doctoral-level study while employed by a health or social care provider or a university, or for a researcher undertaking a doctoral-level study in receipt of a fellowship) take the role of chief investigator at any level of study, as this function should be undertaken by supervisors or course leaders.

If you are a postgraduate student, the PI role may be undertaken by the student who will be under the supervision of a named supervisor. For the purposes of this SOP, the supervisor will be Chief Investigator in such cases and ultimately responsible for the research. If you are an undergraduate or taught Masters student, your project supervisor must be solely responsible and be named as the Chief Investigator.

a) Relevant supervisors (or course leaders, where different) should be encouraged to develop and lead research projects that individual students at master's level and below can contribute to at different stages. Undergraduate students should only

conduct research projects in isolation that involve direct contact with patients, service users or the public in a health or social care setting if on-site supervision arrangements mitigate any risks.

b) A research culture should be fostered amongst relevant undergraduate students by encouraging an awareness of health and social care research, research ethics and public involvement, and enabling them to develop skills in research methods. Students from courses that are not primarily related to health and social care, such as business studies or IT, who wish to undertake research involving patients or service users, their data or tissue, or the public in a health or social care setting should have a co-supervisor with relevant experience that will help them understand the care context and the associated research process.

c) The contribution of students to the development, conduct and reporting of the research should be appropriately acknowledged like that of other contributors, e.g. in accordance with journal editors' authorship criteria.

Standards and Practice

The conduct of clinical research studies is the responsibility of the CI, and the PI at each participating site. The CI and PI may delegate some of their duties as specified on the study's delegation log but the responsibility for ensuring that these duties are carried out remains with them.

The delegation log must be signed and dated by the PI when delegating duties to members of the research team, taking into consideration their evidence of training, education and experience prior to the staff member carrying out any duties for the trial. By delegating duties, the PI confirms that the team member is appropriate for their delegated duties and maintains the responsibility. Active involvement in the study is not permitted for staff until they have been authorised by the PI.

Any changes made to the study delegation log, other than additions and removal of study staff, is to be documented clearly with a corresponding File Note to document

the reason for the change. Staff must ensure that all File Notes are saved in the study's Investigator Site File along with the study delegation log. Any changes must be signed and dated in accordance with GCP guidelines

Absence of Chief or Principal Investigator

For planned absences, the CI or PI is responsible for arranging adequate cover, ensuring the investigator is delegated to the role, trained on the study and the delegation and training log updated appropriately.

For unplanned absences of the CI/PI, the research sponsor together with the site (if the absence is for the PI at the host site) will be responsible for ensuring that appropriate arrangements are made for the continued conduct of the study.

In some cases, it may be necessary to appoint an acting or new CI or PI where the absence is likely to be significant.

As determined by the sponsor, the HRA should be notified by letter about cover arrangements for absent CIs. For PIs, the sponsor and the Trust's R and D function must be notified about cover arrangements for absent PIs.

If the approving bodies have any concerns about the suitability of the arrangements, they should notify the sponsor. They have the discretion to request the formal appointment of an acting CI or PI.

References

UK Policy Framework for Health and Social Care Research - Health Research Authority