1. Introduction and Who Guideline Applies to

Research regulations assign explicit responsibilities to sponsors, host organisations and Investigators for the initiation, management, financing, conduct, monitoring and reporting of clinical research activities.

The UK policy framework for Health and Social Care Research recommends:

- clear designation of responsibility and accountability for those involved in research delivery
- that roles and responsibilities are clearly documented, and agreed and understood by all

This Standard Operating Procedure (SOP) describes the roles and responsibilities of the Chief Investigator (CI) and Principal Investigator (PI) for research studies sponsored or hosted by the University Hospitals of Leicester NHS Trust (UHL).

The aim of this SOP is to ensure that, prior to commencement of any research activity at UHL:

- The **CI** (for UHL Sponsored research) can demonstrate they have the appropriate experience, expertise and training to undertake the design, conduct and analysis of the study to the standards set out in relevant legalisation, and are aware of, and have agreed to, all roles and responsibilities as delegated to them by the study sponsor.
- The **PI** (for UHL Hosted research) can demonstrate they have the appropriate experience, expertise and training to undertake the conduct and delivery of a study to the standards set out in the legislation, and are aware of, and have agreed to, all roles and responsibilities delegated to them by the CI and/or study sponsor.

This SOP applies to all Chief Investigators and Principal Investigators for research hosted by and/or sponsored by UHL.

2. Guideline Standards and Procedures

Definitions

Chief Investigator

The CI is the overall lead researcher for a research project in an area covered by a single competent authority, each country has a separate CI e.g. UK, France, Spain. In addition to any responsibilities as a member of the research team, the CI is accountable for the overall planning, setup, conduct, documentation, and reporting of a research project.

The CI must have demonstrable experience, expertise and training appropriate to the complexity of the research being undertaken, and be able to provide leadership and oversight for staff with delegated responsibilities, ensuring compliance and effective team management.

The CI is accountable to their employer, the study sponsor (if different), and the host organisation where the research takes place. Where research is taking place at more than one location, the CI takes on personal responsibility for the design, management, reporting and coordination of personnel at all participating study locations.

The CI role requires significant commitment and accountability. UHL Research and Innovation (R&I) will provide appropriate support, particularly to individuals undertaking a CI role for the first time.

Principal investigator

A PI is the individual with overall responsibility for the conduct of a research project at a particular research location. There should be one PI for each research location. In the case of a single-location study, the CI and the PI will normally be the same person.

A PI must have demonstrable experience, expertise and training appropriate to the complexity of the research being undertaken, and be able to provide leadership and oversight for all staff with delegated study responsibilities at the study location, ensuring compliance and effective team management.

Research Team

The Research Team is the group of people involved in the conduct of a research project. This may include healthcare professionals, academics, research professionals, students and scientists.

Research Teams are responsible for:

- acquiring any particular knowledge and skills in order to conduct the research
- demonstrating to the Investigator and study sponsors their suitability to conduct the research
- conducting the research according to the approved research protocol, in compliance with any applicable regulatory standards and guidance
- providing information in a suitable format for potential participants that is clear and relevant to their participation in the research and, where consent is required, to their decision-making about taking part in the research
- ensuring participants' safety and well-being in relation to their participation in the research and reporting adverse events where required

2.1 Investigator Responsibilities (PI and CI)

For Clinical Trials of Investigational Medicinal Products (CTIMPs), Investigators must be health professionals, as defined by the Medicines & Healthcare products Regulatory Agency (MHRA) – currently limited to Doctors, Dentists, Nurses and Pharmacists.

Investigators are responsible for ensuring that:

- The research activities they oversee comply with all applicable legislation, institutional policies and ethical standards, and are conducted in accordance with International Conference on Harmonisation guidance for Good Clinical Practice (ICH-GCP).
- Study activity does not start without a favourable opinion from a Research Ethics Committee (REC), HRA approval, Trust (R&I) authorisation and, where relevant, competent authority (MHRA) approval and Sponsor Green Light approval.
- Unless urgent safety measures are necessary, the research follows the protocol or proposal agreed by the relevant REC, HRA, Trust R&I Office and by the Sponsor.
- All researchers with delegated roles in a clinical trial of Investigational Medicinal Products are aware of their legal duties.
- Each member of the Research Team who has direct involvement with participants and/or identifiable data, has an appropriate substantive or honorary contract with a relevant NHS Trust, or an Honorary Research Contract or relevant letter of access via the research passport scheme.

- The Research Team understands the legal and ethical requirements for research and are familiar with the relevant standard operating procedures and policies relating to research.
- The Research Team acts on any conditions attached to the ethics opinion.
- The Research Team gives priority at all times to the dignity, rights, safety and wellbeing of the participants.
- Students and new researchers have adequate supervision, support and training.
- Healthcare professionals responsible for an individual's care are informed if that individual is participating in clinical research. Where 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.

2.2 Principal Investigator Responsibilities

In addition to the Investigator responsibilities listed above, the PI is responsible for ensuring that:

- At their location, the research is set-up, conducted, documented and reported to the required standards, and according to the protocol
- An Investigator Site File (ISF) is created, maintained and kept inspection ready at all times
- All delegated roles and responsibilities are appropriately recorded and undertaken, and that a completed delegation log is held with the ISF.
- The delegation log template provided by the Sponsor is used. If an appropriate log has not been supplied, the UHL Delegation log template can be used. The log can be adapted to define, establish and allocate all study-related duties and functions. The log must:
  - List the names and roles of all staff involved in the research, and outline which duties have been delegated to them
  - Confirm the start and end dates for each staff member performing delegated duties
  - Be signed and dated by the PI, with individual sign-off for each delegated member of staff, prior to them carrying out any trial activity, as evidence that they are qualified by education, training and experience to discharge the duties delegated to them (see SOP C-2005 UHL Training for staff in Hosted Studies). Active involvement in the research is **not permitted** for any staff member until they have been signed-off by the PI.
  - Be updated throughout the study. This may include adding new staff or logging staff who leave. Superseded versions must not be destroyed in order to allow an audit trail of who was performing which duties at any time point in the conduct of the study for future inspection.
  - Be filed appropriately in the Investigator Site File
  - Be supplied to the sponsor as requested

The PI Roles and Responsibilities Declaration (R&I Template T1015) is signed by the PI, unless UHL are the Sponsor and the PI is also the Chief Investigator, in which case the CI Roles and Responsibilities will suffice.

2.3 Chief Investigator Responsibilities

In addition to the Investigator responsibilities listed in Section 4.2, a CI is also responsible for ensuring that:

- A suitable Sponsor is secured, and agreements are in place detailing the responsibilities of all parties involved in the research.
- Potential participants, and other service users and carers, are involved in the design and management of the study whenever appropriate.
- The protocol is submitted for Sponsor review and agreement prior to submitting for REC / HRA review
- The Sponsor has access to the study record on a relevant research database i.e. Clinicaltrials.gov, ISRCTN.
- Authorisation from the R&I Department at each participating care organisation has been obtained, along with Sponsor Green Light, before any research activities commence at a study location.
- Their research is conducted to the required standards and follows relevant frameworks as set out within the UK.
- Each member of the Research Team, including those at collaborating organisations, is qualified by education, training and experience to discharge their role in the study and, where required, their qualifications are documented and retained in the Investigator Site File.
- Where responsibilities have been delegated to members of the research team, this has been clearly documented in a Delegation of Authority Log (template available from R&I). The CI remains accountable for the actions of their Research Team.
- A Trial Master File is created, maintained and kept inspection ready at all times.
- A Roles and Responsibilities document is completed and signed prior to commencement of any part of the research study.
- Substantive changes to the protocol are submitted for Sponsor approval before implementation and prior to ethical, regulatory and Trust authorisation (with the exception of urgent safety measures).
- For clinical trials involving medicines, the research follows all conditions imposed by the licensing authority. The list of responsibilities should be documented in the Sponsorship Agreement.
- Serious Adverse Events are reported to the Sponsor, R&I, REC and the competent authority, as required.
- In accordance with relevant legislation, 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.
- Annual written summaries of the study status are submitted to the Sponsor, REC / HRA and the Competent Authority as relevant, and a final report is provided to the REC at the end of the study. This includes annual reports, end of study declarations, final study reports and safety reporting.

- All appropriate databases i.e. EudraCT, ISRCTN, Clinicaltrials.gov are updated following final report submission within the regulatory time frame.
- Once established, findings from the work are disseminated promptly and fed back as appropriate to participants.
- Arrangements are in place for the management of any intellectual property arising from the research (contact the R&I Office for further advice).
- There are appropriate arrangements in place to retain the TMF/ISF and anonymised data after the research has finished.
- All archived data and documentation relating to the study are available at the request of the inspection and auditing authorities and the Sponsor is kept informed of the location of all retained data, and the contact details of the person responsible.
- Upon receiving Sponsor confirmation that the retention period has expired, appropriate destruction of the TMF/ISF is undertaken in accordance with relevant UHL policies and procedures, and evidence of destruction kept.

3. Education and Training

None

4. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting Arrangement
All research sponsored by UHL has appropriate contracts in place	Included in the monitoring / audit programme	R&I Director of Operations	Random audits / monitoring conducted on research activity	A report will be produced

5. Equality Analysis Assessment

5.1The Trust recognises the diversity of the staff and local community it serves. Our aim therefore is to provide a safe environment free from discrimination, harassment and victimisation and treat all individuals fairly with dignity and respect and, as far as is reasonably possible, according to their needs.

5.2As part of its development, an Equality Analysis on this policy has been undertaken and its impact on equality has been reviewed and no detriment was identified.

6. EDI Statement

We are fully committed to being an inclusive employer and oppose all forms of unlawful or unfair discrimination, bullying, harassment and victimisation.

It is our legal and moral duty to provide equity in employment and service delivery to all and to prevent and act upon any forms of discrimination to all people of protected characteristic: Age, Disability (physical, mental and long-term health conditions), Sex, Gender reassignment, Marriage and Civil Partnership, Sexual orientation, Pregnancy and Maternity, Race (including nationality, ethnicity and

colour), Religion or Belief, and beyond.

We are also committed to the principles in respect of social deprivation and health inequalities.

Our aim is to create an environment where all staff are able to contribute, develop and progress based on their ability, competence and performance. We recognise that some staff may require specific initiatives and/or assistance to progress and develop within the organisation.

We are also committed to delivering services that ensure our patients are cared for, comfortable and as far as possible meet their individual needs.

7. Supporting References

T1015 – Roles and Responsibilities of Principal Investigator Agreement

T1016 – Delegation of Authority & Signature Log

T1017 – Roles and Responsibilities of Chief investigator Agreement

SOP C-2001 – UHL Consent for Hosted Studies

8. Key words

Research and Innovation, Principal Investigator, Chief Investigator, Roles and Responsibilities

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title): Jen Boston, R&I Deputy Director of Operations	**Executive Lead:** Nigel Brunskill
Details of Changes made during review: N/A, new SOP	