1. Introduction

1.1 This Standard Operating Procedure (SOP) describes the role and responsibilities of the Principal Investigator (PI) for research HOSTED by the UHL or where UHL is the research SITE.

1.2 The need for clarity about roles and responsibilities is fundamental to the conduct of research. The Regulations clearly place the responsibility for clinical trials on the sponsor including initiation, management, financing, conduct, monitoring and reporting of data.The outcome is that the PI is aware of and has agreed to all roles and responsibilities as delegated to them by the Chief Investigator (CI) & / or Sponsor prior to the commencement of the research.

1.3 An appropriate individual who has the relevant qualifications and / or experience must be designated as the PI for any research undertaken in or through the NHS or social services or using participants' organs, tissue or data. The PI is the person designated to take overall responsibility for the conduct and reporting of the study at their SITE.

1.4 The PI must ensure that at their SITE 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.

1.5 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. Scope

2.1 This SOP applies to ALL Principal Investigators of studies where UHL is the HOST organisation or research SITE.

3. Procedure

3.1 The PI must be an individual, with appropriate experience, expertise and training to undertake the conduct and delivery of the study to the standards set out in the legislation. They must also lead and manage others at their SITE who have been delegated responsibilities in the research. The need for clarity about roles and responsibilities is fundamental to the conduct of research.

3.2 The PI has overall responsibility for the conduct of the research at their SITE and is accountable to their employer, the Sponsor, and the host organisation where the research takes place.

3.3 The PI is responsible for ensuring all delegated roles and responsibilities are appropriately recorded and undertaken and that all clinical research studies have a current and complete delegation log held with the Investigator Site File (ISF).
The PI should utilise the delegation log template provided by the Sponsor. If an appropriate log has not been supplied by the Sponsor the UHL Delegation log template can be utilised. (Appendix 1 SOP C-2001 Consent for research Hosted by UHL).

3.4 Templates are to be adapted to define, establish and allocate all study-related duties and functions.

3.5 This log is to be used when the PI of a Hosted study onward delegates to individuals in the local research team of the study. The PI can delegate duties, but never the responsibility for the study at the site.

3.5.1 The log must:

- List the names and roles of all staff involved and outline which duties have been delegated to them
- Confirm the start and end dates for each member of staff performing their delegated duties
- Be signed and dated by the PI – they should sign off each individual member of staff, considering their evidence of training, education and experience prior to the staff member carrying out any duties for the trial (see SOP C-2005 UHL Training for staff in Hosted Studies). By delegating duties the PI confirms that the team member is appropriate for their delegated duties and maintains the responsibility. Therefore active involvement in the study is **not** permitted for staff until they have been signed off by the PI.
- Be updated throughout the study. This may include new staff and 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, with updated versions being supplied when updated.

3.6 Principal Investigator

3.6.1 Studies that are approved with effect from 1st April 2019 UHL require that all PIs sign the PI Roles and Responsibilities Declaration (Appendix 1). In cases where UHL are the Sponsor and the Chief Investigator is also the PI, the CI Roles and Responsibilities will be adequate. Where the PI is different to the CI, PI Roles and Responsibilities will be required.

4. Responsibilities

	Responsibility	Undertaken by	Activity
1	Principal Investigator	Principal Investigator	Ensure that any delegated duties are noted appropriately using a Delegation of Authority log.
2	Principal Investigator	Principal Investigator	Ensures all roles and responsibilities are undertaken

5. Who Guideline Applies To

5.1 All staff within UHL and external to UHL who are delivering research.

6. Guideline Standards & Procedures

6.1 The SOP is detailed so the process can be clearly followed. No flowchart is provided / required.

7. Education and Training

7.1 None.

8. Monitoring & Audit Criteria

Key Performance Indicator	Method of Assessment	Frequency	Lead
All research sponsored by UHL has appropriate contracts in place.	Included in the monitoring / audit programme.	Random audits / monitoring conducted on 10% of research activity.	R&I Deputy Chief Operating Officer

9. Supporting Documents and Key References

SOP C-2003 Appendices 1 & 2

SOP C-2001

SOP C-2005

SOP C-2004

10. Key Words

Research, Innovation, EDGE, PI, CI, Responsibilities, Principal Investigator

11. Contact and Review Details

CONTACT AND REVIEW DETAILS	
Guideline Lead (Name and Title) Lisa Wann R&I manager	**Executive Lead** **Medical director**
Details of Changes made during review: **Review and update**	

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

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Carolyn Maloney	**Job Title:** R&I Deputy Chief Operating Officer
Reviewed by:	R&I Management Meeting	
Approved by:	**Professor Nigel Brunskill** DocuSigned by: Nigel Brunskill EB83FF9A871E447...	**Date Approved:** 15-09-2022

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
June 2016	2	CM, LW, AG, SA	Consistency checks. Replace research governance framework with Policy Framework.
February 2017	3	CM	Update to Logo.
February 2019	4	CM, LW	Addition of PI Roles and Responsibilities Declaration – implementation 1st April 2019.
Feb 2021	5	CM,LW,JJ	Addition of delegation log template and clarification of requirements for completion. Updated to new trust template.
Feb 2022	6	LW CS DW	Update

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