Plymouth Research and Development

NHS University Hospitals Plymouth NHS Trust

Standard Operating Procedure

Please refer to https://www.plymouthhospitals.nhs.uk/researchers to ensure the latest version of this document is in use. Printed copies are uncontrolled.

Title:	Investigator responsibilities		
Approver		Document No:	S3
Name:	Chris Rollinson	Version No:	3.0
Signature:		Effective Date:	Jul-2022
Date:	27-Jul-2022	Review Date:	Jul-2025

1. Purpose

To give an overview of the responsibilities of medical 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.

2. Definitions

The **Chief Investigator (CI)** is the authorised health care professional who takes primary responsibility for the conduct of the trial. There is only one CI per EU Member State. 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 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 **Principal Investigator (PI)** is the person who takes responsibility for the initiation and conduct of the study at the local site. There should be one PI at each site participating in a research study. For a single site study, the role of CI may also take on the role of PI.

A **Sub-investigator (Sub-I's)** 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, CI and host site.

The **Study Sponsor** (individual, company, institution, or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial), CI and PI may delegate certain duties but the responsibility for ensuring that these duties are carried out remains with themselves (see SOP P10 Delegation of Duties).

3. Scope

This SOP relates to all CI, PIs and Sub-I's of research hosted by, and/or sponsored by UHP.

4. Responsibilities

The conduct of clinical research studies is the responsibility of the Sponsor, the CI and one PI at each participating site. The CI and PI are also responsible for protecting the rights, safety, and welfare of research participants under their care.

5. Further references

Standard Operating Procedures for Research Ethics Committees. Version 7.5.1, Aug 2021.
https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/RES_Standard_Operating_Procedures_Version_7.5.1_August_2021_Final_Accessible_07lVkXt.pdf

Guideline for good clinical practice E6(R2) Step 5. 14th June 2017 https://www.ema.europa.eu/en/documents/scientific-guideline/ich-e-6-r2-guideline-good-clinical-practice-step-5_en.pdf

UK Policy Framework for Health and Social Care Research. Version 3.3, 7th Nov 2017.
https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/Final_Accessibility_uk-policy-framework-health-social-care-research_.pdf

6. Acronyms

CI: Chief Investigator

CRF: Case Report Form

CTIMP: Clinical Trial of an Investigational Medicinal Product

GCP: Good Clinical Practice

HRA: Health Research Authority

IMP: Investigational Medicinal Product

ISF: Investigator Site File

MHRA: Medicines and Healthcare products Regulatory Agency

PI: Principal Investigator

R&D: Research and Development

REC: Research Ethics Committee

SOP: Standard Operating Procedure

TMF: Trial Master File

TMF: Trial Master File

UHP: University Hospitals Plymouth NHS Trust

7. Procedure

Step	Action	Responsibility
1	**The CI is responsible for ensuring for the whole study 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. • The Trail Master File (TMF) is maintained and kept inspection ready at all times. • 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 (ISF). • 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. • HRA approval received prior to commencing the study at each care organisation and subsequent Trust (R&D) Capacity & Capability statement is obtained from each care organisation • 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, HRA 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	CI

Step	Action	Responsibility
	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 acknowledgement 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.	

Step	Action	Responsibility
	• 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 log. 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.	
2	**The PI is responsible for ensuring for that the local site in a study:** • The research team always gives priority 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 UK Policy Framework for Health and Social Care Research (2017). • The Investigator Site File (ISF) is maintained and kept inspection ready at all times. • 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. • All researcher staff involved in CTIMP studies are aware of their legal responsibilities. • Students and new researchers have adequate supervision, support, and training. • Study does not start without the relevant approvals from the HRA, R&D Capacity and Capability e-mail and Sponsors Green Light (authorisation to begin recruitment). • The research team acts on any conditions to the approval given.	PI

	• Unless Urgent Safety measures are necessary the research team follow the study protocol. • Relevant approval is 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 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. • Report Serious Adverse Events to the Sponsor and R&D 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. • 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 PI delegates responsibilities to members of the research team, this must be clearly documented in a delegation log. The PI remains accountable for the actions of their research team.	
3	**Absence of Chief or Principal Investigator** If Chief Investigators or local Principal Investigators are absent due to annual leave, sick leave, maternity leave, sabbatical or for other reasons. For short absences, the CI or PI is responsible for arranging adequate cover, this maybe in the form of a sub-investigator who has been	Sponsor, CI, PI host site

Step	Action	Responsibility
	appropriately trained on the study and delegated for the role. Where this has not been possible, for example because the absence was unforeseen, the research sponsor together with the site (if PI) 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 exceed 3 months or is indefinite, it is mandatory to appoint an acting or new CI or PI. Where the absence is likely to exceed 4 weeks but will be less than 3 months, the sponsor and or study site should ensure that appropriate cover arrangements are made. The REC should be notified by letter about cover arrangements for absent CIs. For PIs the sponsor and the Trusts R&D office must be notified about cover arrangements for absent PIs. If it has any concerns about the suitability of the arrangements, it should notify the sponsor. The REC has the discretion to request formal appointment of an acting CI or PI. For absences shorter than 4 weeks, it is not generally necessary to notify the REC.	

8. Changes from last revision

Updated template and add new text regarding CI & PI absence.