University Hospitals Plymouth NHS Trust

STANDARD OPERATING PROCEDURE

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION

The definitive versions of all UHPNT RD&I Dept SOPs appear online, not in printed form, to ensure that up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Trust's website: https://www.plymouthhospitals.nhs.uk/researchers

Investigator responsibilities

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Page: **1** of **9**

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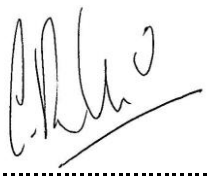
APPROVED BY

Name: Chris Rollinson

Job Title: Research Governance Manager

Signature: 

Date: 18th Jan 2019

1 Purpose and Scope

To give an overview of the responsibilities of medical research investigators.

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.

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).

In scope: All CI & PIs of research hosted by, and/or sponsored by UHPNT.

Definitions

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
TMF	Trial Master File
HRA	Health Research Authority
MHRA	Medicines and Healthcare products Regulatory Agency
REC	Research Ethics Committee
RD&I	Research Development & Innovation
SOP	Standard Operating Procedure
UHPNT	University Hospitals Plymouth NHS Trust
ISF	Investigator Site File

TMF	Trial Master File
PI	Principal Investigator
IMP	Investigational Medicinal Product
CRF	Case Report Form
HRA	Health Research Authority

2 Who should read this document?

All medical staff wishing to become a Chief Investigator (CI) or Principal Investigator (PI).

3 Procedure to Follow

The conduct of clinical research studies is the responsibility of the Sponsor, the CI and one PI at each participating site.

3.1. 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 (RD&I) 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 the relevant ethics committee, by the Trust RD&I 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, RD&I, 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 RD&I 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 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.

3.2. The PI is responsible for ensuring for that the local site in a study:

- 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 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, RD&I Capacity and Capability e-mail and Sponsors Green Light (authorisation to begin recruitment).
- The research team acts on any conditions to the approval given.
- 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, 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.
- Report Serious Adverse Events to the Sponsor and RD&I 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.

4 Document Ratification Process

The review period for this document is set as ***default of three*** years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the ***RD&I Manager or their Deputy***.

Non-significant amendments to this document may be made, under delegated authority from ***a senior RD&I manager***, by the nominated author. These must be ratified by ***a Senior RD&I manager***.

Significant reviews and revisions to this document will include a consultation with ***appropriately knowledgeable staff***. For non-significant amendments, informal consultation will be restricted to ***staff*** who are directly affected by the proposed changes.

Dissemination and implementation

4.1. Dissemination of this SOP

4.1.1. New SOPs and new versions of existing SOPs: The Research Governance Manager will be responsible for ensuring authorised SOPs are uploaded on the RD&I internet site. Internal Trust Staff are expected to use the RD&I internet site to access latest versions of SOPs and to check the website regularly for updates.

Notice of new or amended procedural documents that have undergone a major amendment will be given *via* the following routes:

- Inclusion in the Trust weekly e-bulletin Vital Signs
- Direct email to Trust Researchers and or teams

4.2. Training in this SOP

4.2.1. All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP.

5 Reference material

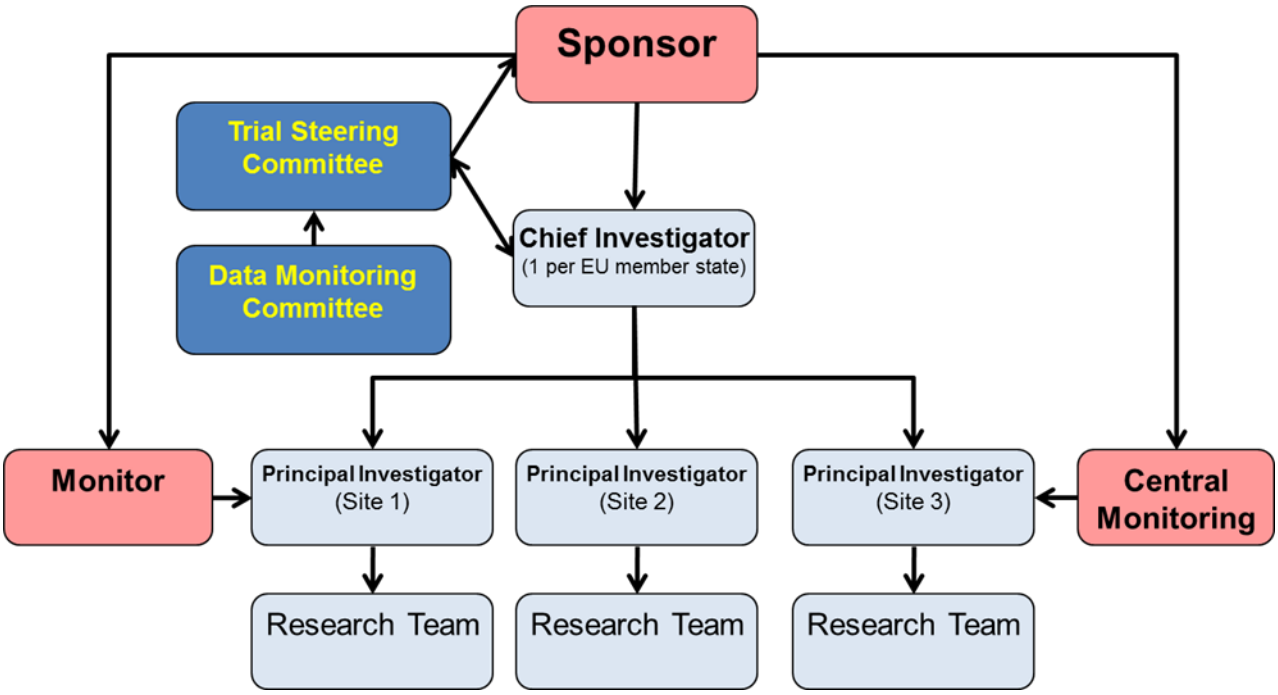
All members of the research team shall comply with all current clinical trial and medical device regulations applicable to the performance of the project, including:

Data Protection Act (2018)

Human Tissue Act (2004)

The Mental Capacity Act (2005)

Appendix: Diagram illustrating the roles in study oversight — Appendix 1



6 Amendment History

Version Number:	2.1
Date Of Amendment:	Jan 2019
Details Of Amendment:	Updated Trust and Dept. name. Reduce signature requirement to single senior RD&I Manager. Removed references to clinical trial and medical device regulations. Updated references to the Data Protection Act 2018.

Version Number:	2.0
Date Of Amendment:	Aug 2017
Details Of Amendment:	Update SOP template and numbering. SOP reviewed and re-written.