RD&I	NHS 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/research-sops

Study start up

SOP No: T1

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Page: **1** of **10**

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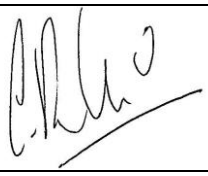
Signature:	
Date:	21st Jan 2019

1 Purpose and Scope

This SOP describes the start-up procedure for a clinical research study.

UHPNT as the Sponsor will be responsible for setting up study sites. The Sponsor may delegate the responsibility for performing certain study site set-up activities to the study CI who may in turn delegate appropriately trained and qualified members of the research team, and this will be recorded in the Study Delegation Log.

Where the study is run on behalf of the Sponsor by a Clinical Trials Unit, an agreement between the Sponsor and the Trials Unit shall set out the responsibilities for performing study activities. In turn, the Clinical Trials Unit may delegate responsibility for some of these activities to the CI and this will be recorded in the Study Delegation Log.

In scope: research hosted by, and/or sponsored by UHPNT. This SOP applies to all healthcare research sponsored by UHPNT which falls within the scope of the UK Policy Framework for Health and Social Care Research (2017). Where additional legislation applies - for example the Medicines for Human Use (Clinical Trials) Regulations 2004 (and amendments) or the Medical Devices Regulations 2002 - required procedures will be indicated. External sponsors may require use of their own SOPs and this will be specified in site agreements. It is the responsibility of the local PI to ensure that study specific SOPs can be operated without conflict with this SOP and in accordance with all organisational policies related to research.

Definitions

PI	Principal Investigators
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
GCP	Good Clinical Practice
HCA	Health Care Assistants
HRA	Health Research Authority
MHRA	Medicines and Healthcare products Regulatory Agency
REC	Research Ethics Committee
RD&I	Research, Development & Innovation
RO	Research Office

SOP Standard Operating Procedure

UHPNT University Hospitals Plymouth NHS Trust

2 Who should read this document?

All staff involved in setting up and conducting research e.g. Chief Investigators (CI), Principal Investigators (PI), Research Nurses & Midwives, Health Care Assistants (HCA), RD&I Managers and Clinical Trial Administrative staff

3 Procedure to Follow

The RD&I may be contacted at any point for help and support. RD&I can be reached *via* email: plh-tr.RD-Office@nhs.net

All research studies will have to be submitted for HRA Approval[1] and HRA guidance must be followed, see www.hra.nhs.uk/resources/hra-approval-applicant-guidance . Application and submission will occur *via* IRAS. For further details, see www.myresearchproject.org.uk . HRA approval will not be issued until all other relevant regulatory approvals (e.g. REC/MHRA) are in place.

[1] HRA Approval is the new single application process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by the HRA, with the independent REC opinion provided through the UK Health Department's Research Ethics Service. All project-based research taking place in the NHS in England is required to obtain HRA Approval. Studies with sites in Northern Ireland, Scotland or Wales will be supported through existing UK-wide compatibility systems, by which each country accepts the centralised assurances, as far as they apply, from national coordinating functions without unnecessary duplication.

3.1. Requesting RD&I Confirmation

Submission and review of requests occurs in three main stages**: *Feasibility, Arrangement*** and ***Confirmation.*** The Sponsor (or their nominated delegate) is responsible for submitting the relevant paperwork to allow each stage to commence. If the study is sponsored by UHPNT, the CI is responsible for submitting these documents. All documents should be submitted to RD&I *via* plh-tr.RD-Office@nhs.net . Each section is outlined below, including details of the relevant paperwork to be submitted at each stage, and what subsequently happens at each stage.

3.1.1. Feasibility:

I. Initial *Assessment* involves RD&I liaising with researchers and other key stakeholders to identify whether it is feasible that UHPNT will have the capability and capacity to deliver the research study.

II. This assessment can occur when a protocol is submitted to RD&I *via* email. This should be the final version that will be (or has already been) submitted for HRA Approval.

III. Once the final protocol is received by RD&I, the study will be given an RD&I reference number and registered on the EDGE Database (if not already registered). If the study is a Trust sponsored study RD&I will assigned a member of the RD&I team to act as your first point of contact throughout the RD&I process.

IV. Assessment will be based upon an assessment covering:

a. Participant population.

b. Staff requirements.

c. The equipment/space/specialist services/emergency processes/safety reporting processes/IT etc. needed to deliver the study.

V. Once assessment outcome is positive and site selection is confirmed between Sponsor and RD&I (*via* email), further documentation will be required to progress into the '*Arrangement*' stage (see below).

VI. If the assessment outcome is that UHPNT are not likely to have the capacity and capability to deliver the study, this will be communicated with the sponsor and UHPNT will not proceed to set up as a site.

3.1.2. Arrangement:

I. RD&I must make arrangements to enable local capacity and capability to deliver the research study. To initiate this stage, all documents as indicated below must be submitted to RD&I by email once the research study has received a HRA Initial Assessment Letter (or HRA Approval Letter where no Initial Assessment letter is issued):

a. Copy of IRAS Form (combined REC and RD&I form) as submitted for HRA Approval.

b. Protocol.

c. Any amendments.

d. Participant information and consent documents.

e. Statement of Activities (SoA) relevant to the participating NHS organisation (non-commercially sponsored studies only).

f. Relevant template contract/model agreement (if needed in addition to Statement of Activities).

g. Costing template (commercially sponsored studies only) or Schedule of Events [(SoE) non-commercially sponsored studies only].

h. Any other documents that the Sponsor wishes to provide to the site to support the set up and delivery of the study.

i. HRA Initial Assessment letter (if one is issued) and (when issued) HRA Approval letter and final document versions.

II. RD&I will put in place the arrangements to deliver the study. These arrangements may include, but are not limited to:

a. Ensuring any HRA guidance (as indicated in Initial Assessment/Approval) is acted on;

b. Putting in place any necessary contractual arrangements;

c. Negotiation and agreement of financial arrangements;

d. Ensuring that there are adequate resources are available at UHPNT from commencement to completion of the research - including finance, staff, and facilities (e.g. Pharmacy, Radiology, laboratories and other support departments);

e. Ensuring that all research staff possess the necessary level of access and are trained by education and experience for their roles in research, see SOP on Honorary Research Contracts & Letters of Access;

f. Ensuring Research Governance compliance is met by local research team members.

III. Where the following documents are not already held by RD&I, local research personnel will be asked to submit the following to RD&I during this assessment stage:

a. A *Curriculum Vitae* (CV) dated within the last 2 years; and

b. A valid Research Governance (GCP) certificate - UHPNT policy indicates these are valid for 2 years from date of issue.

IV. It is likely that RD&I will need to contact the research team and Sponsor with queries during the arrangement process. It is essential that the research team/Sponsor co-operate fully with any such queries, as this prevents delay during study set up. Research teams may be asked to provide information about study feasibility using the EDGE Database (UHPNT's research management system) and guidance will be offered on how this is done.

3.1.3. Confirmation:

I. In order for Confirmation of local capability and capacity to be obtained, final HRA approved versions of the documents and/or Statement of Activities will be required. This should be submitted to RD&I by email.

II. Confirmation can only occur once HRA Approval is obtained and UHPNT is ready to start the study. Confirmation will be provided *via* email to all relevant parties.

III. Subject to all relevant actions being completed, RD&I Confirmation will be issued alongside full execution of all agreements/ Statement of Activities. This is issued electronically *via* email to the PI, Sponsor, and research team.

IV. Once RD&I Confirmation is given, the research can proceed at UHPNT, subject to relevant compliance as indicated on the confirmation email.

3.2. Site initiation

Site initiation must be completed prior to recruitment and prior to any trial procedures that require informed consent. A site may be deemed initiated once:

- All essential documents and approvals are in place according to Sponsor requirements. This includes any local approvals, study contracts and protocol agreement.
- Investigator(s) are familiar with study requirements, relevant regulations/frameworks and roles/responsibilities.
- The site has been provided with relevant documentation, equipment and/or training to enable site staff to begin trial conduct and recruitment.
- Randomisation system is in place, if applicable.
- For CTIMPs, the study drug is available to the site and adequately stored. Study drug must not be available to a particular site until approvals are in place for that site and the site has undergone a documented green light process.

3.2.1. Site initiation visits

Site Initiation Visits (SIVs) are a monitoring activity and required prior to recruitment and any trial procedures that require participant informed consent.

3.2.2. Before the initiation visit

The Trial Manager will liaise with RD&I and the study research team to organise a date for the initiation visit and make sure that key members of the site team are available. Depending on the size of the study and number of sites, the CI or delegate(s) may also attend. The site team should include wherever possible: Principal Investigator (PI), co-investigators, local co-ordinators, nursing staff and any others involved in the study e.g. surgeons, radiologists, pharmacists, laboratory staff, data managers, representatives from RD&I. A specific visit to pharmacy or local laboratories may need to be incorporated to review specific Investigational Medicinal Product (IMP) or sample requirements.

The Trial Manager, CI and/or delegate will prepare the SIV slides (version controlled) prior to the initiation visit. The Trial Manager should provide a copy of the slides to the site team prior to the initiation meeting.

The Trial Manager should confirm all relevant details of the forthcoming initiation visit in writing. The site should retain the original correspondence within the Investigator Site File (ISF) and the Trial Manager should ensure a copy is filed in the Trial Master File (TMF).

3.2.3. Study documentation and supplies

ISF, Case Report Forms (CRFs) and all other study documentation and supplies should be on site when the site initiation visit is conducted. If not, the Trial Manager should discuss the date they will be sent to the site at the visit.

Attendance at the SIV must be clearly documented through a completed initiation visit attendance sheet that has been signed by all present. The Trial Manager must ensure the original is filed in the TMF.

3.2.4. Following the initiation visit

Details of site initiations must be documented and the Trial Manager should complete a Site Initiation Report to include the visit date, site, name of persons in attendance, summary of any issues discussed and outstanding queries. A copy of the report should be provided to the CI, sponsor and the study research team. The original signed report should be held in the TMF, along with a copy of the initiation slides, site follow-up letter and attendance details. Any issues raised must be followed up promptly to closure. Once issues are resolved, the Trial Manager should complete a green light checklist, which must be signed off by the sponsor representative before the site can be deemed initiated. Once the green light checklist has been signed off by the sponsor, the site should be notified in writing that they are deemed initiated and may commence recruitment. The signed green light checklist should be filed in the TMF.

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 intranet site. Internal Trust Staff are expected to use the RD&I intranet 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

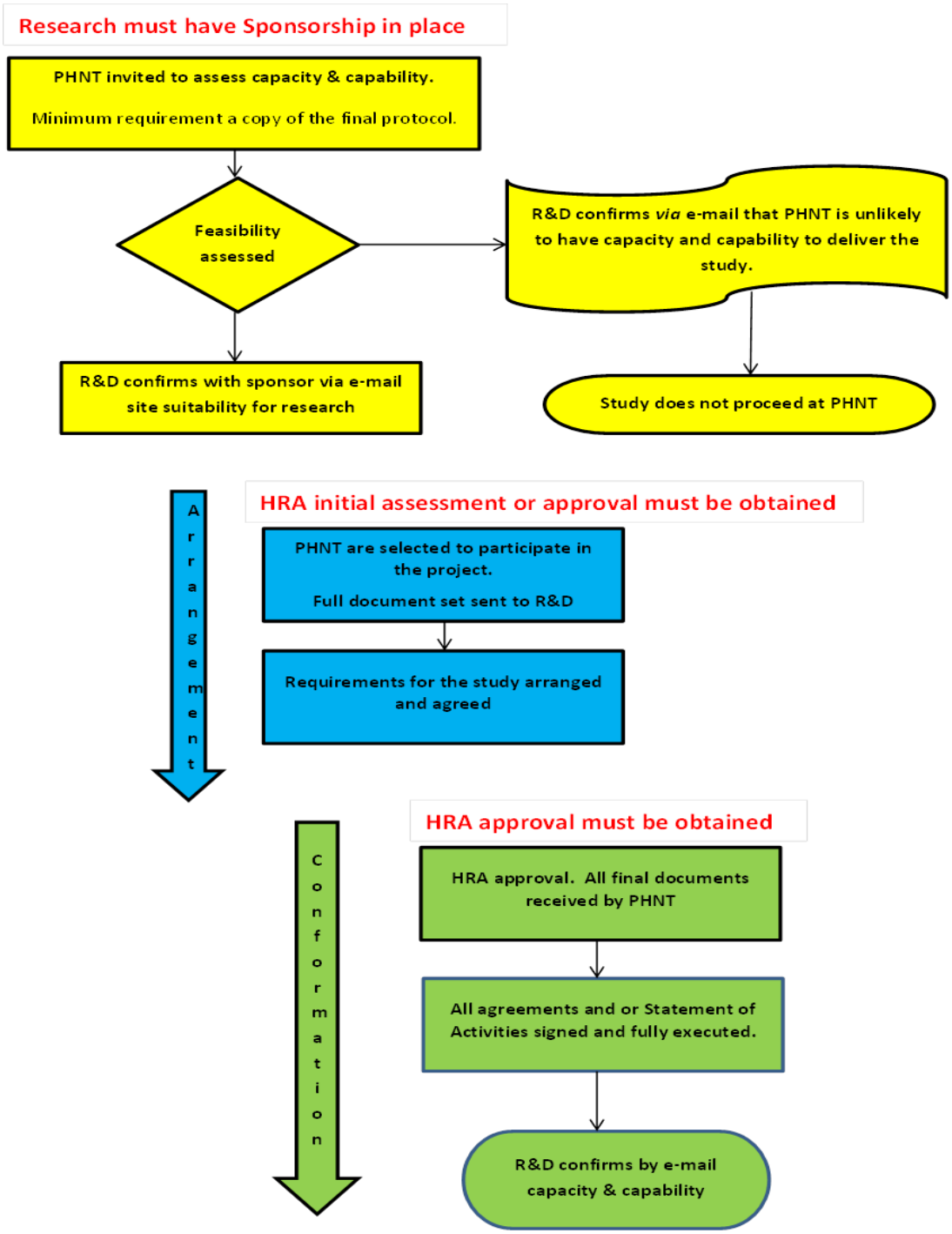
4.2. Training in this SOP

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

Health Research Authority: *Decision Tool for Research*
www.hra.nhs.uk/research-community/before-you-apply/determine-whether-your-study-is-research

Appendix: Start up process — Appendix 1



6 Amendment History

Version Number:	1.1
Date Of Amendment:	Jan 2019
Details Of Amendment:	Updated Trust and Dept. name including Dept. e-mail address. Reduce signature requirement to single senior RD&I Manager. Updated references to the UK Policy Framework for Health and Social Care Research (2017).