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

Clinical trials staff shortages during pandemic & epidemic disease - Contingency Plan

SOP No: P&E2

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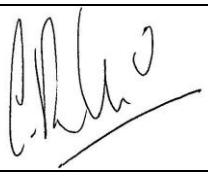
Signature:	
Date:	18th Jan 2019

1 Purpose and Scope

The purpose of this Standard Operating Procedure (SOP) is to outline a plan of action to ensure that the Sponsor and Chief / Principal Investigator responsibilities for ongoing trials are met throughout a period during which a disease is pandemic or epidemic and a serious risk to human health or potentially a serious risk to human health leading to a shortage of staff resources.

In scope: research hosted by, and/or sponsored by UHPNT.

Definitions

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
PenCTU	Peninsula Clinical Trials Unit
UHPNT	University Hospitals Plymouth NHS Trust
PI	Principal Investigators
PUPSMD	Plymouth University Peninsula Schools of Medicine and Dentistry
RD&I	Research Development & Innovation
REC	Research Ethics Committee
RO	Research Office
SOP	Standard Operating Procedure
UoP	University of Plymouth

2 Who should read this document?

All staff involved in 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

It is very difficult to predict the impact on clinical trial activity during a full pandemic situation as it will be complicated by trial staff being re-deployed to assist with core healthcare activities, as well as potential illness amongst the trial teams and the trial subjects. Where trial activity continues Sponsors are expected to continue to meet their obligations with respect to clinical trials legislation, guided where necessary by advice from the MHRA website and Pandemic Situation helpline, as the situation develops.

3.1. Pandemic Working Party

Once a pandemic situation has been declared, the RD&I management team will form the Pandemic working party. This will include: -

- RD&I Director.
- Senior members of the RD&I Management Team (RD&I Manager, Lead RD&I Research Nurse (or Deputy), Research Operations Manager, Research Advisor and Trust IP lead and the Research Governance Manager).

However, due to the very nature of a pandemic this may not be possible to achieve, in which case members may be drawn from other senior members of the RD&I Dept and appropriate experienced Trust and University researchers.

The working party will be tasked with the following: -

1. Review the portfolio of clinical trials, in the first instance all trials in the set up or planning phase will be put onto hold and available RD&I resource directed to ongoing trials.
2. Each ongoing trial will be reviewed to ensure that sufficient clinical resource is available to ensure patient safety and data integrity is maintained. Appropriately trained deputy CI/PI's will be identified and briefed at this stage in case of existing CI/PI absence.
3. Clinical resource must be allocated to trials with patients enrolled into intervention phases of trials. It may be necessary for trials that have single dosing episodes to be temporarily suspended to allow for those trials with subjects in longer term active phases to be resourced adequately.
4. Each trial will be reviewed with the CI to discuss temporary suspension of recruitment to ensure adequate safety and monitoring of existing patients on trials.

5. Pooling of organizational research nurse resources should be considered to ensure the rights, safety and well-being of enrolled subjects and data integrity is maintained.
6. RD&I management team to keep local Investigators informed on situation.

3.2. Amendments to HRA, REC & MHRA

Non-substantial amendments do not need to be reported to the MHRA but do require HRA approval before implementing. Substantial amendments should be notified to the HRA, MHRA and concerned Ethics Committee in the normal way.

3.3. Emergency Safety Measures

The MHRA have confirmed that all Sponsor and CI responsibilities must be met during a pandemic situation, however, the sponsor and Investigator may take appropriate urgent safety measures in order to protect the subjects of a clinical trial against any immediate hazard to their health or safety.

Any such action taken will be reported to the MHRA within 3 days.

3.4. SUSARS, SAE's & Adverse Events

The MHRA expect Sponsors to continue to meet their obligations with respect to clinical trials legislation, including Pharmacovigilance reporting, guided where necessary by advice from their website and helpline, as the situation develops.

Pandemic disease related AEs/SAEs must be recorded in the CRFs as they are reported unless the Sponsor can justify a substantial amendment to the protocol which excludes reporting this type of event. The amendment would require approval by the MHRA in the normal way and the appropriate REC.

3.5. Protocol Deviations & Serious Breach Reports

All protocol deviations should be recorded in the CRF, and serious breaches recorded for reporting when the situation allows this to be done.

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

MHRA Pandemic Situation Questions & Answers
http://www.khpcto.co.uk/Documents/SOP/PANDEMIC%20CONTINGENCY%20PLAN/ASSOCIATED%20DOCUMENTS/Pandemic_QAs_FINAL[1].pdf

6 Amendment History

Version Number:	2.2
Date Of Amendment:	Dec 2020
Details Of Amendment:	Updated Section 3.1 on the pandemic Working Party.

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.

Version Number:	2.0
Date Of Amendment:	Jul 2017
Details Of Amendment:	Updated SOP template and numbering system. SOP reviewed and updated.