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

Arranging expedited NHS permission of studies relating to urgent pandemic and epidemic research.

SOP No: P&E1

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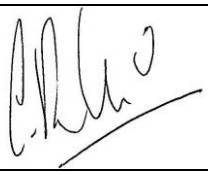
Signature:	
Date:	18th Jan 2019

1 Purpose and Scope

This SOP outlines the process to be followed when arranging expedited NHS permission of studies which meet certain criteria outlined by the Department of Health and National Institute for Health Research (NIHR) for urgent research into pandemic or epidemic diseases.

Urgent public heath outbreaks can cause serious risk to human health. In the event of an urgent public health outbreak (e.g. a pandemic or epidemic) the National Institute for Health Research (NIHR) Clinical Research Network (CRN) must be able to rapidly set-up relevant research studies and ensure that these studies are successfully conducted so that their findings can inform the on-going care of patients during the outbreak.

This will require some changes to the usual processes undertaken by the CRN and NHS Trusts, as well as the reprioritisation of both national and local resources in what may well be a challenging environment in terms of increased demands for patient care and falling staff numbers because of illness.

Consequently, the NIHR has an urgent public health plan in place to ensure that urgent public health studies can be set-up and delivered quickly and effectively.

In scope: urgent research into pandemic or epidemic diseases hosted by, and/or sponsored by UHPNT. The SOP is for use by the Research and Development Department and Trust authorised signatories for issuing Trust NHS permission for research

Definitions

PI	Principal Investigators
CRN	Comprehensive Research Network
RM&G	Research Management & Governance
POC	Point Of Contact
NIHR	National Institute for Health Research
LCRN	Local Clinical Research Network
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 NHS Trust

2 Who should read this document?

All staff involved in setting up urgent research into pandemic and epidemic diseases of national and international importance e.g. Chief Investigators (CI), Principal Investigators (PI), Trial Co-ordinators / Mangers, RD&I Managers and RD&I Clinical Trial Administrative staff.

2.1 Responsibilities.

Arranging Trust:	Approval is undertaken by a nominated person.
RD&I Manager:	Final sign off of the study (or appropriate delegate representative).
Support departments:	Review study documentation and sign off.
The Divisional/Deputy Divisional/Clinical Director:	Review study documentation and sign off.
Communicable Diseases Working Group (if set-up):	Review the study if required.

3 Procedure to Follow

3.1. National procedure

The CRN's urgent public health risk process will be activated at the request of the Department of Health. It will begin with the identification of relevant studies.

The CRN will expedite the approvals for those studies identified as relevant to the urgent public health risk. These studies will be given priority status and the relevant approvals will be granted within six working days. This includes rapid confirmation that the study is eligible for CRN support.

Commercial studies approved and identified by the Department of Health as relevant to the urgent public health risk will also be given priority status by the CRN and feasibility review will be completed within seven working days. Study set-up will be expedited and operationally managed by the Local Clinical Research Network (LCRN) teams. Oversight and coordination will be provided by the national Clinical Research Network Industry team.

3.1.1. Delivering urgent public health studies

The aim of the CRN during an urgent public health outbreak will be to deliver identified research studies in an efficient and timely manner. This will involve both the national Clinical Research Network Coordinating Centre and the LCRN. Studies identified as urgent public health will be excluded from the NIHR Clinical Research Network high level objective of first patient, first visit.

3.1.2. On-going reporting and monitoring arrangements

Daily***** meetings of the CRN Urgent Public Health Group will take place to monitor the progress and delivery of the identified research studies.

*******or at a frequency determined by the severity of the situation*

3.2. The following sections provide a description of the local procedures.

3.2.1. Governance process for CRN adopted studies

- The RD&I Manager (or appropriate delegate representative) will be notified of an expedited approval study by the local CRN.
- They will inform the RD&I Office staff who will then prioritise and start the process of registering the study.
- Expedited governance checks will be carried out as per the Trust Research Approval Process.
- The need for contracts will be assessed by the RD&I team and where appropriate Trust NHS Permission may be granted subject to the relevant contracts (for transfer of tissue/data/funding) being put in place.

3.2.2. Governance process for non CRN adopted studies

- Any member of staff within the RD&I Department who is informed of an expedited approval study will notify the RD&I Manager (or delegated representative).
- They will inform the RD&I Office staff who will prioritise and begin the process of registering the study.
- Expedited governance checks to be carried out as per Trust Research Approval Process.
- The need for contracts will be assessed by RD&I and where appropriate Trust NHS Permission may be granted subject to the relevant contracts (for transfer of tissue/data/funding) being put in place

3.2.3. Support department signatures

- All signatures must be obtained within 1 day
- upon receipt of the study protocol the RD&I Office staff will:
  - Assess which support departments will be involved
  - Who will need to review the study
- The study protocol, along with any other relevant documentation will be e-mailed to the Point of Contact (POC) by the RD&I Manager (or appropriate delegate representative), or in their absence, by a nominated person.
- Any flags that can be set within Microsoft Outlook in order to prompt a response will be used.
- Within 1 hour of sending the documentation a follow up phone call and/or e-mail will be made by the RD&I Manager (or appropriate delegate representative) where any issues with the application will be discussed
- If the support department has no objection, the nominated person will collect the necessary signatures from each POC
- If any support department(s) raises an objection that cannot be resolved after discussions have taken place with the RD&I Manager (or appropriate delegate representative), the local CLRN Lead RM&G Manager must be informed
- For non-portfolio studies the PI and/or CI will be informed
- All reasonable effort must be made to resolve any issues to allow Trust NHS Permission of the study to be given
- In the event of any serious issues concerning the study whereby the Trust is unable to give approval an e-mail detailing the reasons and/or concerns will be sent to the Lead RM&G Manager or CI/PI for non-portfolio studies
- In the event of any issues delaying the approval process, every effort must be made by the support department to resolve any problems with the researchers and keep the RD&I Department updated on timelines.

3.2.4. Directors signatures

- The updated Divisional Directorates and Clinical Departments list is sent by the Medical Directors office regularly to the RD&I enquiries e-mail account and is saved on the RD&I network
- The RD&I office staff must ensure that they refer to the most recent version
- Upon receipt of the study protocol RD&I office staff will assess which Divisional Directorates will be involved and which Director will need to review the study
- The application form and study protocol, along with any other relevant documentation, will be e-mailed to the relevant Director by the RD&I Manager (or appropriate delegate representative)
- The same process for obtaining signatures from support departments will be followed

3.2.5. Contacts and signatories

- There must be 2 POC's and 2 named authorised signatories for each support department.
- If under exceptional circumstances all authorised signatories are on annual leave or are not available, the nominated person will establish when a signature can be obtained and determine with the CI/PI whether this will delay the start of the research at the Trust.
- The Lead RM&G Manager should be contacted an made aware of the situation for Portfolio studies if an unacceptable delay will occur due to absence of the signatories.

3.2.6. Incident management team (Communicable Disease Working Group)

- If set-up the Communicable Disease Working Group should be chaired by the Trust Chief Operating Officer.
- Any studies that meet the expedited approval criteria must be reviewed by this group, who will then provide feedback/advice to the RD&I Manager
- Their role will be to review the logistics of the study to ensure that operationally the Trust is able to accommodate the research proposed

3.2.7. Turnaround time

- The Trust Capacity & Capability statement can only be issued once a favourable opinion from ethics and if applicable a notice of acceptance has been received from the MHRA.
- All governance checks should be carried out as soon any documentation is received so that there is no delay in issuing the Trust Capacity & Capability statement.

- Should there be a failure to receive the required documentation; the RD&I office staff must make every effort to contact the researchers
- Should contact not be successful, RD&I office staff will visit the researcher and collect the missing paperwork

3.2.8. RD&I cover

- Should the RD&I Manager and/or nominated person not be available the following people will provide cover:
- RD&I Manager: As signatory for Trust NHS Permission: Director of RD&I, Deputy RD&I Manager or Research Governance Manager.
- For other responsibilities relating to this SOP: For CLRN portfolio studies – Lead RM&G Manager, Research Governance Manager or Commercial Trials Manager; For Non CLRN portfolio studies – Research Governance Manager or Deputy RD&I Manager.
- The term 'Nominated Person' relates any RD&I Office staff member.

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

NIHR Clinical Research Network urgent public health risk planning
https://www.nihr.ac.uk/nihr-in-your-area/primary-care/documents/Urgent%20Public%20Health%20Research%20Process%20Summary.pdf

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.

Version Number:	2.0
Date Of Amendment:	Aug 2017
Details Of Amendment:	Updated SOP template and numbering system. Reviewed and update SOP.