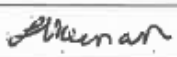
STANDARD OPERATING PROCEDURE

S63
PROCESS FOR EXPEDITING URGENT PUBLIC HEALTH RESEARCH AND THE MANAGEMENT OF R&D ACTIVITIES INCLUDING STAFFING ARRANGEMENTS DURING A PANDEMIC

Version	3
Effective Date	23rd September 2021
Review Date	22nd September 2024
Author & Position	Samantha Keenan, Acting Lead Research Nurse
Signature	
Date	24.9.2021
Approver & Position	Helen Quinn, R&D Director
Signature	
Date	27-9-2021

Controlled document

This document has been created following the Royal Devon and Exeter NHS Foundation Trust Policy for the Development, Ratification & Management of Procedural Documents. It should not be altered in any way without the express permission of the author or their representative.

It is the responsibility of all users of this SOP to ensure that the correct version is being used. If you are reading this in a paper format please go on-line to confirm you have the latest version.

DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless a study specific SOP exists.

Once printed this is an uncontrolled document

Full History			
Version	**Date**	**Author**	**Reason**
1.0	5 December 2014	Anoushka Tepielow	
1.1	27 September 2016	QA Coordinator for R&D	• Copyright symbol removed from front page • Change of Author • Updated link to online SOPs on the new Hub Intranet, live from August 2016
2	5 March 2020	Acting Lead Research Nurse	• Review & update
3	14 September 2021	Acting Lead Research Nurse	• Review and update

Associated Trust Policies/ Procedural documents:	• NIHR CRN SWP Urgent Public Health Research Delivery Plan SOP 11 V1.0 June 2019 • RDEFT Emergency Preparedness, Resilience and Response Policy • R&D Service Continuity Plan
Key Words:	Public Health
In consultation with: Governance Oversight Group (GOG)	

Contents

1 INTRODUCTION

The National Institute for Health Research Local Clinical Research Network (NIHR LCRN) will be informed by the Department of Health and Social Care (DHSC) when the need for urgent public health research has been identified. The studies identified by DHSC will then need to gain Health Research Authority (HRA) approval and for NHS Trusts to undertake Assess, Arrange and Confirm activities as quickly as possible. These 'expedited' studies will be given priority both by the NIHR and HRA. It is anticipated that the process will enable the first HRA permission within a study to be granted within six days.

It is important that there are contingency plans in place in the event of any pandemic and that urgent public health research is expedited and that all R&D activity is managed appropriately. The plan takes account of likely staff absences and continuity of services so that appropriate studies can be processed and delivered.

2. PURPOSE

This SOP explains the contingency plans for preparing for pandemic outbreak and the processes in place for expediting permission for urgent research as well as the processes for ensuring continuity of R&D services in the event of staff absences.

3. SCOPE

This SOP describes the procedure for preparing for urgent public health research at the Royal Devon and Exeter NHS Foundation Trust (RDEFT).

4. DEFINITIONS

CTU	Clinical Trials Unit
CRF	Clinical Research Facility
GOG	Governance Oversight Group
R&D	Research & Development
SOP	Standard Operating Procedure
RM&G	Research Management & Governance
HRA	Health Research Authority
DHSC	Department of Health and Social Care
NIHR	National Institute for Health Research
LCRN	Local Clinical Research Network
RDEFT	Royal Devon and Exeter NHS Foundation Trust
SAE	Serious Adverse Event
SWP	South West Peninsula
SUSAR	Suspected Unexpected Serious Adverse Reaction

5. DUTIES AND RESPONSIBILITIES OF STAFF

This SOP is applicable for Research Management & Governance (RM&G) and research delivery staff within the Trust.

RM&G staff have responsibility for expediting the approval of Urgent Public Health Research and supporting other activity.

The Lead Research Nurse for clinical trials has responsibility for ensuring delivery staff are available to deliver Urgent Public Health Research and that staff are also available to support other essential R&D delivery activities.

6. PROCEDURES

6.1 Expediting RM&G permission

The NIHR CRN South West Peninsula Urgent Public Health Research Delivery Plan SOP 11 V1.0 in conjunction with the RDEFT Emergency Preparedness, Resilience and Response Policy and Research & Development's Service Continuity Plan should be followed.

6.2 Ensuring Delivery of Urgent Public Health Research

Research & Development (R&D) and the Clinical Trials Delivery Team (including the CRF) are responsible for implementing NIHR Prioritised Urgent Public Health Research and will work in collaboration with the relevant clinical and infection control teams to ensure appropriate recruitment is achieved.

The Lead Nurse for Clinical Trials is responsible for overseeing the delivery workforce and will put into place a relevant plan dependant on the nature of study and the availability of the workforce at that time. This review will be done in liaison with the Clinical Trials Delivery Team Leads, one of which will be nominated to coordinate in the absence of the Lead Nurse. Staff from the Clinical Trials Delivery Team will be allocated to support delivery of the Urgent Public Health Research dependant on the number of staff available and the needs of current trial participants. Where the trial involves working on "closed" wards, staff will be allocated considering their health and wellbeing and will refrain from working on "clean" wards during the same day.

In the event of a pandemic, to oversee the management of research delivery including potential redeployment of staff to support the delivery of Urgent Public Health Research and usual clinical care, an oversight group will be convened. They will review the portfolio, the group will incorporate key staff including but not limited to the R&D Director, Deputy Director,, Research Governance and Quality Manager, Lead Research Nurse, CRF Senior Nurse or Operations Manager, Senior Administrator and a Data Assistant. The purpose of this group is to review the situation, the current portfolio and propose actions to manage the service including:

- At all times take account of current Trust and national guidance in making recommendations

- All open studies will be reviewed and categorised as follows:

a) research where clinical care is research protocol dependant and considered safe/in participants best interest to proceed with enrolment and/or study visits if resources allow.
b) research where clinical care is research protocol dependant and it is considered there will be a time point when risk to participants outweighs benefits of continuation with enrolment and/or study visits regardless of resources.
c) research where the protocol may increase the risk if the participant were to contract the pandemic disease or may increase the risk of contracting the disease
d) non-urgent research (e.g. non pandemic observational studies)
e) pandemic research

The priorities will be studies in categories (a) and € with a focus also on patient safety visits,

- All activity will continue until the oversight group consider activities should be scaled back or suspended taking in to account the severity of the pandemic and impact on clinical services (appendix 1).
- CI/PIs will be asked to support R&D to categorise studies, and to work with the research teams to review and manage delivery. Decisions regarding suspending or delaying studies will be communicated to CI/PI's.
- All participants enrolled in a regulated trial or an interventional trial subject to safety reporting will be identified, with protocol-related activities taken in to account to plan workforce and support service requirements to ensure all safety requirements are met including required reporting.
- A core establishment will be identified to ensure essential safety visits, tests and procedures can be delivered.
- Using the criteria above and in response to the evolving pandemic situation, studies will remain open to recruitment, suspend recruitment to maintain follow-up activity or be temporarily suspended depending on circumstances at the time.
- Study set-up may be paused where required and in response to the evolving pandemic situation
- Many professional services staff activity can be delivered remotely; remote access to be secured for the Research Quality and Assurance Manager, Deputy R&D Manager and at least two administrators
- R&D will inform study sponsors of decisions to suspend screening or recruitment and will continue to update sponsors on any changes to study status.
- Identify participant visits that can be postponed and rearranged or conducted via teleconference or videoconference.
- Ensure regular communication with pharmacy and support services are maintained, providing information on the level of demand for that service for medication or other essential tests and procedures to identify any problems with resupply or access to services at an early stage.
- An action tracker will be maintained to document prioritisation of studies, staffing requirements and actions..

6.3 Reduction of Staffing

Should there be staffing shortages, the on-going care of clinical trial participants is paramount and staff will be relocated, following review and prioritisation of the portfolio by the oversight group as outlined in 6.2.

In the event of more than 30% of staff being unable to attend work in a team then the following actions should be taken by the most senior person within the team:

- Notify the Lead Clinical Trials Research Nurse and Research & Development Director. Initial notification may be by phone but this will be confirmed by email.
- The oversight group will review and prioritise the portfolio as outlined in 6.2 on a regular basis
- The Lead Clinical Trials Research Nurse and CRF Operations Manager and Senior Research Nurse will work closely together to manage workforce across the portfolios
- Where it is not possible for the Trust Clinical Delivery Teams or CRF staff to undertake essential safety visits, tests and procedures the PI should be contacted in the first instance and then the Trust Assistant Directors of Nursing to find out availability of cover from clinical service, where appropriate.
- Contact CRN SWP Lead Research Nurses to find out availability for cover from another Trust.

7. DISSEMINATION AND TRAINING

7.1 This SOP and associated templates and forms will be uploaded to the RDE Research website shortly after having been released.

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

7.3 *If applicable, a training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the contents of this SOP.*

8. MONITORING COMPLIANCE AND EFFECTIVENESS OF THIS SOP

8.1 In order to monitor compliance with this SOP, the auditable standards will be monitored as follows:

No	Minimum Requirements	Evidenced by
1.	Review of the current portfolio has taken place with prioritisation of studies, redeployment of staff & actions of workforce team documented.	Core Team action tracker
2.	R&D Director was notified of reduction in staffing by email.	Email
3.	Reduction of workforce by more than 30% evidenced.	Workforce development report

8.2 Outcomes from audit will be presented to the R&D Governance Oversight Group (GOG) which will monitor any resulting action plans until all issues have been addressed to satisfaction.

8.3 Issues identified via the audit process which require escalation will be referred to GOG.

9. ARCHIVING ARRANGEMENTS

9.1 The original of this document will remain with the R&D Quality Assurance Coordinator. An electronic copy will be maintained on the R&D section of the Q-Pulse document management system and a pdf copy on the RDE Research website.

9.2 Archive copies must be maintained for any documents which have been superseded. Archive copies in electronic format should be retained indefinitely.

10. REFERENCES

Appendix 1

Stage 1: Preparation	Stage 2: Limited research activities	Stage 3: Essential activity
Review all active studies and those in set-up to identify those which may require special attention, i.e. those • related directly to the pandemic • where clinical care is research protocol dependent • which may put participants at increased risk of the pandemic infection and/or of more severe illness if infected Review all studies to determine minimum staffing levels to provide essential safety and protocol related care	• Suspend set-up of new studies* • Suspend recruitment to all studies* • Suspend studies which may put participants at increased risk of the pandemic infection and/or of more severe illness if infected • Continue study visits for participants already recruited to other studies, minimising their visits to the site as required e.g. by carrying out remote follow-up where possible * With the exception of those related directly to the pandemic and those where clinical care is research protocol dependent	All activities suspended for all studies, with the exception of those: • related directly to the pandemic • where clinical care is research protocol dependent