STANDARD OPERATING PROCEDURE

PROCESS FOR DEALING WITH URGENT PUBLIC HEALTH RESEARCH S63

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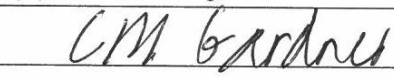
Signature:	

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DISCLAIMER

This generic R&D Standard Operating Procedure (SOP) must be followed unless;

- A study specific SOP exists
- A departmental SOP dictates a different working practice

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VERSION HISTORY LOG

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

VERSION	Reviewer	Date Implemented	Details of significant changes
1.0	Anoushka Tepielow	5 December 2014	
1.1	Lisella Wilkinson, QA Coordinator for R&D	27 September 2016	• Copyright symbol removed from front page • Change of Author • Updated link to online SOPs on the new Hub Intranet, live from August 2016

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1. BACKGROUND

The Comprehensive Research Network (CRN) will be informed by the Department of Health when the need for urgent public health research has been identified. The studies identified by the Department of Health will then need to gain NHS permission as quickly as possible. These 'expedited' studies will be given priority both by the Networks and in the National Institute for Health Research (NIHR) Coordinated System for gaining NHS Permission (CSP). It is anticipated that the process will enable the first NHS permission within a study to be granted within six days, providing all regulatory approvals are in place.

It is important that there are contingency plans in place in the event of any flu pandemic and that urgent public health research is expedited. The plan also takes account of likely staff absences and continuity of services so that studies can still be processed and delivered.

2. PURPOSE

This SOP explains the contingency plans for preparing for pandemic flu outbreak and the processes in place for expediting permission for urgent research.

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. RESPONSIBILITIES

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.

The Lead Research Practitioner has responsibility for ensuring delivery staff are available to deliver Urgent Public Health Research.

5. PROCEDURES

5.1. Expediting RM&G permission

The Peninsula Comprehensive Local Research Network (PenCLRN) SOP16: Pandemic Flu Planning and Research Management and Governance should be followed.

5.2 Ensuring Delivery of Urgent Public Health Research

The Lead Research Practitioner for Clinical Trials is responsible for overseeing the Clinical Trials Workforce and will put in place a relevant plan dependant on the nature of study and

the availability of Clinical Trials Workforce at that time. This will be done in liaison with the Team Leads and a Team Lead will be nominated in the absence of the Lead Practitioner.

Staff from the clinical trials team will be allocated to recruit to 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.

5.3 Reduction of Staffing

Should there be staffing shortages, the on-going care of clinical trial participants is paramount and staff will be relocated in order to ensure the welfare of current participants. This may require the temporary suspension of recruiting new trial participants to non-urgent NIHR portfolio research.

In the event of more than 30% of staff being unable to attend work for up to 2 weeks then the following actions should be taken by the most senior person within the team:

- Notify the Research & Development (R&D) Directorate Manager
- Find out which patients have research appointments booked for which trials for the next two weeks
- Find out if there are trial set up activities that are time critical
- Review availability of staff within other speciality teams
- Contact Lead Research Nurse for Trust to find out availability of cover from CRF team.
- Contact Trust Assistant Directors of Nursing to find out availability of cover from clinical service.
- Contact Pen CLRN Lead Research Nurses to find out availability for cover from another Trust.

Arrangements should be made to cover workload by prioritising delivery of trials and utilising available appropriately qualified staff from other teams. Activity outside maintaining on-going trials can be suspended. If it proves impossible to cover workload using RD&E staff only, then NIHR Research staff based in other Trusts in the region can be considered.

Patients booked in for research appointments take first priority. If the member of staff scheduled to see the patient is not there then another appropriately qualified member of staff should take on the research visit, conducting it according to the trial protocol and instructions located in the study site file.

Prioritise processing of SAEs and SUSARs reporting to meet legal timelines.

Screening activity can continue to be undertaken if capacity allows and all patient visits and exceptional events reporting has been covered.

Non-essential activity should be suspended until the team has capacity to resume activity. Trial set up activity can be prioritised if there are pertinent deadlines to be met.

Routine study processing of studies can continue to be undertaken if capacity allows and all time critical actions have been covered.

Escalation plans should be agreed with the relevant Team Lead and be reviewed daily.

6. RELATED DOCUMENTS

- The PenCLRN SOP 16: Pandemic Flu Planning and Research Management and Governance.
- CRN Urgent Public Health Research Plan

Appendix 1 – Abbreviations

CRN - Comprehensive Research Network
CSP - Coordinated System for gaining NHS Permission
NHS – National Health Service
NIHR - National Institute for Health Research
PenCLRN - Peninsula Comprehensive Local Research Network
R&D – Research & Development
RD&E – Royal Devon & Exeter
RDEFT - Royal Devon and Exeter NHS Foundation Trust
RM&G – Research Management & Governance
SAE – Serious Adverse Event
SOP – Standard Operating Procedure
SUSAR – Suspected Unexpected Serious Adverse Event