Royal Papworth Hospital
NHS Foundation Trust

Document Title: Expedited Trust Approval of Urgent Public Health Research Studies

Document Number: PTUC SOP070

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Administration Manager, Clinical Project Managers
Document author/owner:	R&D Administration Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
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Summary of Significant Change(s) (for this version only)

Section(s):	Modification:
	Additions to section 1

Key Points of this Document

- This document sets out the procedures to be followed by all Papworth Staff who are involved in the expedited trust approval of Urgent Public Health Research Studies.
- It aims to provide clear guidance on the steps to be followed to facilitate rapid trust approval of Urgent Public Health Research Studies while ensuring full compliance with the Research Governance Framework for Health and Social Care (2005).

1 Purpose and Contents

a. The Department of Health may identify the need for Urgent Health Research to be expedited, for example, in a pandemic situation. The Chief Operating Officer of the CRN will initiate the Urgent Public Health Plan as detailed in 'CRN Urgent Public Health Research Plan - 1. Initiation of Urgent Public Health Plan.'

b. The request to expedite trust approval for designated Urgent Public Health Research studies will be cascaded through the Clinical Research Network, reaching Papworth Hospital via the Eastern network central RM&G team.

c. The R&D department, Papworth Hospital, will be requested to complete trust approval in a specified number of hours or days.

d. This document describes the Trust's procedures for expediting local governance and feasibility review of new Urgent Public Health Research Studies.

e. It aims to provide clear guidance on facilitating appropriate review of feasibility, finances and contractual arrangements in a much shortened timeline while continuing to meet the Trust's responsibilities with respect to the Research Governance Framework for Health and Social Care (2005).

1.1 While HRA Approval will be the single approval for research in the NHS in England, there is still an expectation that researchers will engage with sites and that sites will confirm that they have all the arrangements in place in order to participate in the study. Sites confirm all arrangements are in place through execution of a trial agreement or agreement to the Statement of Activities by an appropriately authorised person from the organisation.

1.2 HRA Approval provides a proportionate approach to study set-up. There are therefore some study types for which the HRA will advise that there is no obligation for participating organisations to confirm their capacity and capability to participate. The sponsor may assume their confirmation after a set time period if no objection is made. This will apply in situations where the impact of the study on the organisation is minimal or for urgent public health studies where time is of the essence and the NHS is expected to respond. In circumstances where this applies, it will be clearly stated in the HRA Approval Letter and all sites to which it applies will be directly notified by the HRA, ensuring that they have the opportunity to consider opting out of the study if appropriate.

2 Roles & Responsibilities

a. This Policy applies to all personnel that are conducting research at the Trust including: staff that are full or part-time employees of the Trust, those working at the Trust with employment contracts funded partially or wholly by third parties including those within CUHP AHSC and those seconded to and providing consultancy to the Trust, and to students undertaking training at the Trust.

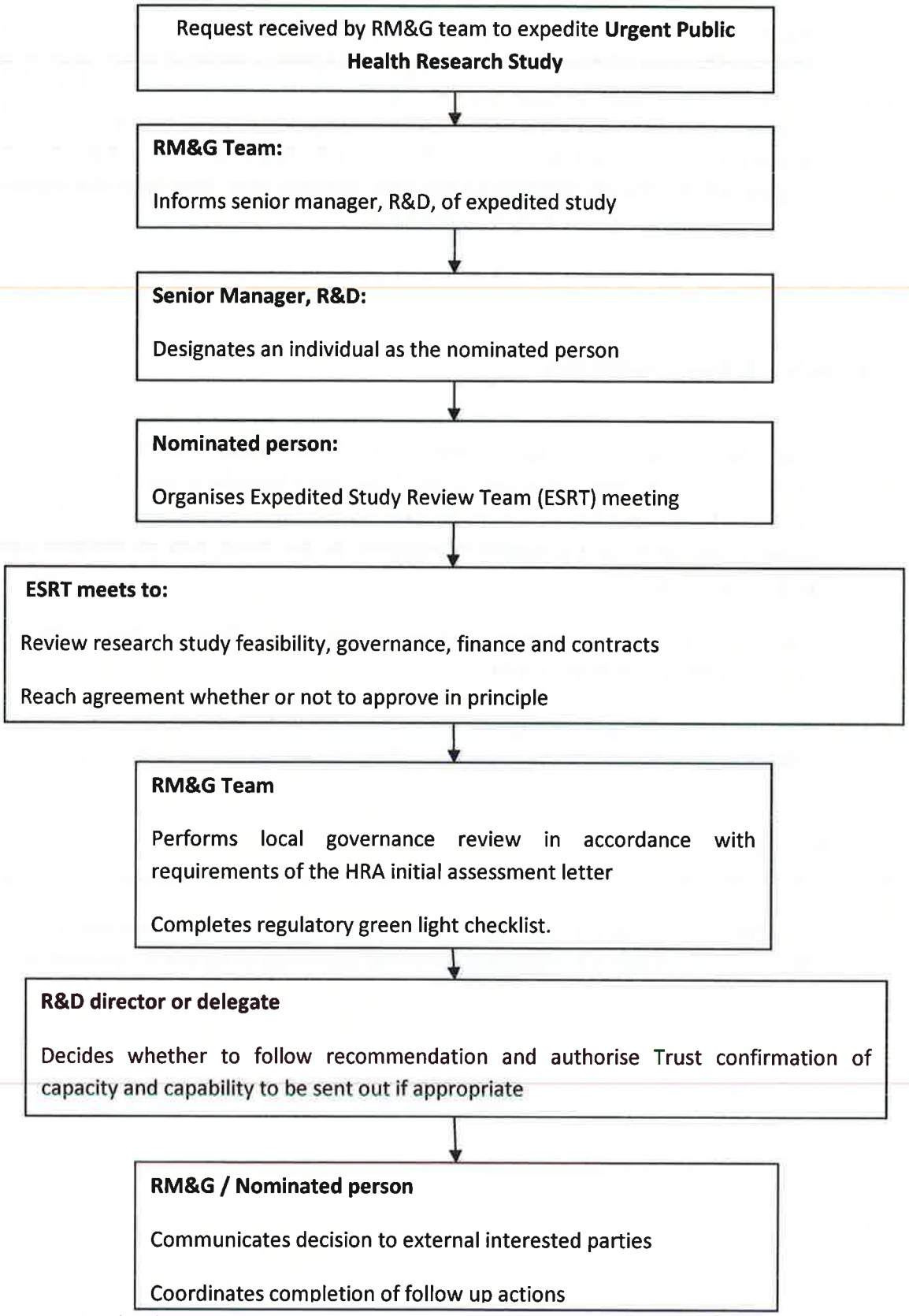
b. Staff involved in trust approval of Urgent Public Health Research must comply with the requirements set out in section 3a.

c. It is the responsibility of the department's personnel to ensure that they are familiar with and adhere to all current SOPs, and have signed the relevant log in their training record.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with may result in disciplinary procedures.

4. Procedure


Request received by RM&G team to expedite **Urgent Public Health Research Study**
RM&G Team:
Informs senior manager, R&D, of expedited study
Senior Manager, R&D:
Designates an individual as the nominated person
Nominated person:
Organises Expedited Study Review Team (ESRT) meeting
ESRT meets to:
Review research study feasibility, governance, finance and contracts
Reach agreement whether or not to approve in principle
RM&G Team
Performs local governance review in accordance with requirements of the HRA initial assessment letter
Completes regulatory green light checklist.
R&D director or delegate
Decides whether to follow recommendation and authorise Trust confirmation of capacity and capability to be sent out if appropriate
RM&G / Nominated person
Communicates decision to external interested parties
Coordinates completion of follow up actions

4.1 Request received to expedite local trust approval

a. Eastern CRN RM&G will notify the RM&G team at Papworth Hospital of a new Urgent Public Health Research study and request that trust approval is expedited.

b. Eastern CRN RM&G will advise the RM&G team of study title, IRAS number, REC reference, timelines and any other relevant information.

4.2 R&D senior manager informed

a. The RM&G team informs the senior manager, R&D, or delegate, of the request for expedited review of the Urgent Public Health Research study.

b. The senior manager, R&D, or delegate, designates the nominated person and establishes timelines.

4.3 Expedited Study Review Team (ESRT) identified

a. The nominated person reviews available information and documentation in sufficient detail to determine:

1. Clinical area, CI, PI and research team
2. Directorates and service departments affected.

b. The nominated person identifies the most suitable individuals to form the ESRT.

c. The ESRT consists of:

1. A Senior Manager, R&D
2. A Clinical Project Manager
3. A RM&G representative
4. The nominated person
5. If available, Research Nurse / Trial Co-ordinator appropriate to the clinical area
6. If appropriate, representatives from Pharmacy and Radiology.

d. The nominated person organises the ESRT meeting in a suitable timeframe and distributes available information and documents.

e. The ESRT should preferably meet face to face, but may meet via telephone or email exchange as necessary.

4.4 R&D director informed

a. The nominated person informs the R&D Director or delegate of the Urgent Public Health Research study and arranges an appointment to meet and present the ESRT recommendation (see 4.7a below).

4.5 Expedited Study Review Team meeting convened

a. The ESRT meets to review and assess study feasibility, governance, finance and contracts.

b. The team identifies major areas of concern that would significantly impact on the ability of the Trust to deliver the study. Minor issues will be noted as items to follow up post approval.

c. The team agrees a risk assessment rating.

d. The team agrees the directorate and service department authorisations required prior to trust approval.

e. The team reaches an agreement to either:

1. Recommend trust confirmation of capacity and capability in principle
2. Decline trust involvement.

f. The team agrees an action plan, identifying actions requiring completion prior to trust approval.

g. The nominated person documents areas of concern, items to follow up post approval, the action plan and decisions made.

4.6 RM&G activities

a. The Urgent Public Health Research Study is registered on the research database. See SOP035.

b. If the ESRT has agreed a recommendation to recommend trust approval in principle:

1. A Regulatory Green Light checklist is completed, as detailed in SOP034 Trust Approval and Research Governance, taking into account output from the ESRT meeting and satisfactory completion of actions.
2. A Trust confirmation of capacity and capability email is prepared.

4.7 Trust approval decision

a. The nominated person presents the ESRT recommendation, plus supporting information, to the R&D director, or delegate.

b. The R&D director or delegate decides whether to follow the ESRT recommendation.

c. If appropriate The R&D director or delegate authorises the Trust confirmation of capacity and capability email to be sent.

4.8 Following the trust approval decision

a. The nominated person notifies the PI and research team of the decision and, if the decision has been made to approve the study, emails the PI and research team the Trust confirmation of capacity and capability.

b. The nominated person informs Eastern CRN RM&G of the decision.

c. The RM&G team coordinates completion of follow up actions.

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the senior R&D Manager should be gained before any action is taken. SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

Further Document Information

Approved by: *Management/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current active version approved date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. Research Governance Framework for Health and Social Care (2005)
Key related documents:	Trust Research Policy SOP034 Trust Approval and Research Governance SOP035 Research Database Application (ReDA)

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

Review date:	November 2020

Version Control

Version	Date effective	Valid to	Approved by	Date of approval
1.0				
2.0				
3.0				
4.0				

I certify the contents of this SOP has been reviewed and ratified

..... 10th January 2018

Signed by Dr Ian Smith, Clinical Director of R&D — Date

SOP release date: 15th January 2018