

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

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Summary of Amendments

| Version Number | Modification: |
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| V3.0 | Minor amendments throughout |
| V4.0 | Changes to terminology |
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| Key related documents: | SOP034 Trust Confirmation of Capacity and Capability and Sponsor Green Light Notification to Conduct Research Studies SOP035 Using the Local Portfolio Management system (EDGE) FRM013 Risk Assessment |
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Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth Staff who are involved in the expedited Trust approval (Confirmation of Capacity and Capability) of Urgent Public Health Research Studies.
- It aims to provide clear guidance on the steps to be followed to facilitate rapid review, set up, and Confirmation of Capacity and Capability of Urgent Public Health Research Studies while ensuring full compliance with the UK Policy Framework for Health and Social Care.

1 Purpose and Contents

- a. The Department of Health and Social Care (DHSC) may identify the need for Urgent Public Health (UPH) Research to be expedited, for example, in a pandemic situation. The Chief Operating Officer of the Research Delivery Network (RDN) will initiate the Urgent Public Health Plan as detailed in the 'East of England Regional Research Delivery Network Urgent Public Health Research Delivery Plan.'
- b. The request to expedite Trust set up and Confirmation of Capacity and Capability for designated UPH Research studies will be cascaded through the RDN, reaching Royal Papworth Hospital via the Regional Research Delivery Network (RRDN) East of England network via R&D Enquiries (papworth.randdenquiries@nhs.net) or Senior Manager of the R&D department.
- c. Where deemed applicable, the R&D department at Royal Papworth Hospital, will be expected to perform expedited local governance review, and issue Trust Confirmation of Capacity and Capability in a specified number of hours or days.
- d. This document aims to provide clear guidance on facilitating expedited review of feasibility, and contractual arrangements in the required timeline while continuing to meet the Trust's responsibilities with respect to the UK Policy Framework for Health and Social Care.
- e. e Where Royal Papworth Hospital is a sponsor for studies deemed as UPH, the sponsor team shall follow the HRA guidance on fast track approvals process.
- f. 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 Site Agreement or Organisation Information Document (OID) by an appropriately authorised person from the organisation.

- g. 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 UPH 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.

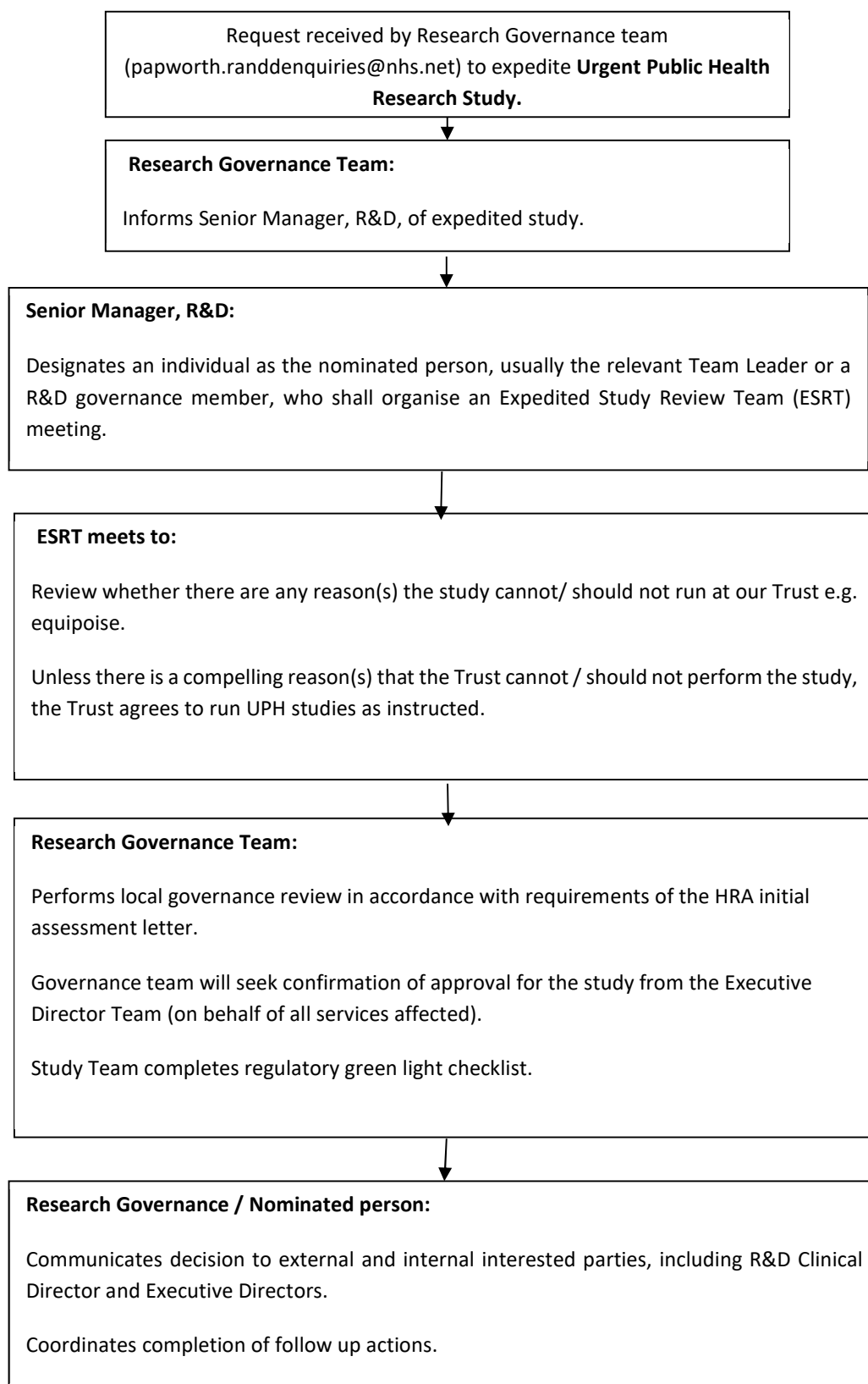
2 Roles & Responsibilities

- a. This Policy applies to all personnel that are conducting research at the Trust.
- b. Staff involved in the set up and Trust Confirmation of Capacity and Capability process of UPH Research must comply with the requirements set out in section 4.
- 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



4.1 Request received to expedite Trust Confirmation of Capacity and Capability

- a. RRDN East of England will notify the Research Governance team at Royal Papworth Hospital of a new UPH Research study and request that the Trust Confirmation of Capacity and Capability process be expedited.
- b. RRDN East of England will advise the Research Governance team of study title, IRAS number, REC reference, timelines and any other relevant information.

4.2 R&D Senior Manager informed

- a. The Research Governance team informs the Senior Manager of R&D, or delegate, of the request for expedited review of the UPH Research study.
- b. The Senior Manager of R&D, or delegate, designates the nominated person and confirms 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, 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. The Senior Manager, R&D, or delegate
 - 2. Principal Investigator, or delegate
 - 3. A Research Governance representative
 - 4. The nominated person (if different from above)
 - 5. Team Leader or Research Nurse / Trial Co-ordinator appropriate to the clinical area
 - 6. If appropriate, representatives from Pharmacy, Radiology and any other required support services.
- d. The nominated person organises the ESRT meeting in a suitable timeframe and distributes available information and documents.

4.4 Expedited Study Review Team meeting convened

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

- b. The ESRT 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 ESRT identifies if there are significant risks associated with the study. If the study has significant risks identified an action plan may be formulated and agreement reached on whether the study requires adding to the Trust risk register. In any case, a formal risk assessment may be completed later (FRM013).
- d. The ESRT agrees the directorate and service department authorisations required prior to Trust Confirmation of Capacity and Capability. This may be expedited via Executive Director approval on behalf of the services.
- e. The ESRT reaches an agreement to either:
 - 1. Recommend Trust Confirmation of Capacity and Capability in principle
 - 2. Decline Trust involvement
- f. The ESRT agrees an action plan, identifying actions requiring completion prior to Trust Confirmation of Capacity and Capability.
- g. The nominated person documents areas of concern, items to follow up post approval, the action plan and decisions made.

4.5 Research Governance activities

- a. The UPH Research Study is registered on the research database. See SOP035 Using the Local Portfolio Management System (EDGE).
- b. If the ESRT has agreed a recommendation to recommend Trust Confirmation of Capacity and Capability in principle:
 - 1. Appropriate governance checks applicable to the study are completed prior to issuing Trust Confirmation of Capacity and Capability, taking into account output from the ESRT meeting and satisfactory completion of actions.
 - 2. A Trust Confirmation of Capacity and Capability email is prepared.

4.6 R&D Clinical Director informed

- a. The nominated person informs the R&D Clinical Director or delegate of the UPH Research study and present the ESRT recommendation (see **Error! Reference source not found.** below).

4.7 The Trust Confirmation of Capacity and Capability 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, the Research Governance team issues the Trust Confirmation of Capacity and Capability email to the PI, research team, impacted services and Sponsor.
- b. The Research Governance 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

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| Approved by: <i>Management/Clinical Directorate Group</i> | | Research and Development Directorate | | | | | |
| Approval date: <i>(this version)</i> | | Current active version approved date | | | | | |
| Ratified by Board of Directors/Committee of the Board of Directors: | | STET | | | | | |
| Date: | | N/A | | | | | |
| This document supports: <i>Standards and legislation</i> | | Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research (2023) | | | | | |
| 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 | | | | | | | |
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