Standard Operating Procedure R&D/SOP007

Expedited Trust Approval Process

1. **Scope**
   For use by the Research and Development department and Trust authorised signatories for issuing Trust NHS Capacity and Capability for pandemic or epidemic research.

2. **Purpose**
   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, LCRN, R&D Department etc. This will mainly relate to studies relating to pandemic and epidemic research.

3. **Definitions and Abbreviations**
   The headings below contain the definitions of terms and meaning of abbreviations used within the document.

3.1. **Definitions**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>Adopted Study</td>
<td>Adopted on to the NIHR Research Portfolio</td>
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<tr>
<td>Portfolio Study</td>
<td>A study which has been adopted onto the NIHR Research Portfolio</td>
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<tr>
<td>Nominated person</td>
<td>Research Governance Coordinator or Assistant</td>
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3.2. **Abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Meaning</th>
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<tbody>
<tr>
<td>LCRN</td>
<td>Local Clinical Research Network</td>
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<tr>
<td>C&amp;C</td>
<td>Trust Capacity and Capability</td>
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<td>HRA</td>
<td>Health Regulatory Authority</td>
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<tr>
<td>EPIC</td>
<td>Epic Systems Corporation (E-Hospital)</td>
</tr>
<tr>
<td>CUH</td>
<td>Cambridge University Hospitals</td>
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4. **Undertaken by**

**Arranging Trust:**
Approval is undertaken by a nominated person

**R&D Manager:**
Final sign off of the study (or appropriate delegate representative)

**Support departments:**
Review study documentation and sign the study assessment form
Research and Development Box 277

The Divisional/Deputy Divisional/Clinical Director:
Review study documentation and sign the study assessment form

Communicable Diseases Working Group:
Review the study if required

5. Items Required
UK Policy Framework for Health and Social Care Research 2017

6. Summary of Significant Changes
General review and update, changes in response to HRA incorporation

7. Method
The following sections provide a description of the processes to be followed when implementing this document’s procedures.

7.1. Governance Process for NIHR Portfolio Adopted Studies
- The R&D Manager (or appropriate delegate representative) will be notified of an expedited approval study by the local CRN
- They will inform the Nominated Person who will then start the Trust's process for issuing Capacity and Capability (C&C) Governance checks will be carried out as per the Trust's process for C&C
- The need for contracts will be assessed by the legal team and where appropriate Trust NHS C&C may be granted subject to the relevant contracts (for transfer of tissue/data/funding) being put in place

7.2. Governance Process for Non NIHR Portfolio Adopted Studies
- Any member of staff within the R&D Department who is informed of an expedited approval study will notify the R&D Manager (or delegated representative)
- They will inform the Nominated Person who will begin the process of registering the study
- Governance checks to be carried out as per the Trust's process for C&C The need for contracts will be assessed by the legal team, where appropriate Trust NHS Permission may be granted subject to the relevant contracts (for transfer of tissue/data/funding) being in place

7.3. Support Department Signatures
- All signatures must be obtained within 1 day
- Upon receipt of the Local Information Pack the Nominated Person will:
  - Assess which support departments will be involved
  - Who will need to review the study
- The application form, study protocol, along with any other relevant documentation will be e-mailed to the support department representatives
by the R&D Manager (or appropriate delegate representative), or in their absence, by the 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 R&D 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 support department representative
- If any support department(s) raises an objection that cannot be resolved after discussions have taken place with the R&D Manager (or appropriate delegate representative), the LCRN contact 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 Trust C&C an e-mail detailing the reasons and/or concerns will be sent to the LCRN contact or CI/PI for non-portfolio studies
- In the event of any issues delaying the C&C process, every effort must be made by the support department to resolve any problems with the researchers and keep the R&D Department updated on timelines

7.4. Directors Signatures

- The updated Divisional Directorates and Clinical Departments list is sent by the Medical Directors office regularly to the R&D enquiries e-mail account and is saved on the R&D network
- The nominated person must ensure that they refer to the most recent version
- Upon receipt of the Local Information Pack the Nominated Person will assess which Clinical Divisions will be involved and which Director should 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 R&D Manager (or appropriate delegate representative)
- The same process for obtaining signatures from support departments will be followed

7.5. Contacts and Signatories

- There are named authorised Speciality Leads, Academic Research Leads, Clinical Director or Divisional Director signatories covering 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
7.6. Incident Management Team (Communicable Disease Working Group)

- The Communicable Disease Working Group is chaired by the Director of Operations
- Any studies that meet the expedited approval criteria must be reviewed by this group, who will then provide feedback/advice to the R&D 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

7.7. Turn Around Time

- Trust NHS C&C can only be issued once a favourable opinion from the HRA has been received
- All governance checks should be carried out as soon any documentation is received so that there is no delay in issuing Trust NHS C&C
- Should there be a failure to receive the required documentation; the nominated person must make every effort to contact the researchers
- Should contact not be successful, the nominated person will visit the researcher and collect the missing paperwork

7.8. R&D Cover

- Should the R&D Manager and/or nominated person not be available the following people will provide cover:
  - R&D Manager: As signatory for Trust NHS C&C: Director of R&D or Research Governance Manager/Lead

8. Monitoring Compliance with and the Effectiveness of this Document

a. Process for Monitoring Compliance and Effectiveness
   As part of routine monitoring visits, audit and inspection

b. Standards/Key Performance Indicators
   This process forms part of a quality management system and is reviewed according to CCTU procedures. Standard Operating Procedures are reviewed every two years.

9. References

The Institute of Clinical Research, Abbreviations used in Clinical Trials.
MHRA, Good Clinical Practice “Grey Guide”

10. Associated Documents

UK Policy Framework for Health and Social Care Research 2017
11. **Equality and Diversity Statement**

This document complies with the Cambridge University Hospitals NHS Foundation Trust service equality and diversity statement.

12. **Disclaimer**

It is the user’s responsibility to check against the electronic library that this printed out copy is the most recent issue of this document.

<table>
<thead>
<tr>
<th>Review date</th>
<th>3 years (or earlier in light of new evidence) from approval date</th>
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<td>Owning department:</td>
<td>CCTU QA</td>
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<tr>
<td>Supersedes:</td>
<td>R&amp;D/SOP007 v2</td>
</tr>
<tr>
<td>Local reference:</td>
<td>R&amp;D/SOP007 v3</td>
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