

**STANDARD OPERATING PROCEDURE**

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**Expedited Trust Approval Process**

**R&D/S/020/1.0**

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**Author:** Jo Heritage – Information Manager

**Approved By:**

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Stephen Kelleher - R&D Manager

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Date

**Effective Date:** 17 March 2010

**Review date:** This will be two years from the effective date

**Copy Number:**

**1. PURPOSE AND SCOPE**

This SOP outlines the process to be followed when arranging expedited NHS approval of studies which meet certain criteria outlined by the Department of Health, CLRN, R&D Department etc. This will mainly relate to studies relating to pandemic and epidemic research.

**2. ASSOCIATED DOCUMENTS**

NIHR CRN SOP titled Recording Comments for Governance Checks in CSP ReDA – current version

NIHR CSP Operating Guidelines – current version

Research Governance Framework 2<sup>nd</sup> edition 2005

**3. RESPONSIBILITIES**

Nominated Person – will be responsible for arranging Trust approval for the study.

R&D Manager – responsible for having final sign off of the study

Support departments – to review study documentation and to sign the SSI form

Divisional/Deputy Divisional/Clinical Director – to review study documentation and to sign the SSI form

Communicable Diseases Working Group – to review study, if required

**4. PROCEDURES****4.1 GOVERNANCE PROCESS FOR CLRN ADOPTED STUDIES**

The R&D Manager will be notified of an expedited approval study by the local CLRN.

The R&D Manager will inform the Nominated Person who will then start the process of registering the study.

For studies where we are the lead site - see appendix 1

For studies where we are a participating site - see appendix 2

Governance checks will be carried out as per NIHR CRN SOP titled 'Recording Comments for Governance Checks in CSP ReDA' and the NIHR CSP Operating Guidelines.

**4.2 GOVERNANCE PROCESS FOR NON CLRN 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.

The R&D Manager will inform the Nominated Person who will begin the process of registering the study.

Governance checks to be carried out as per Research Governance Training Manual v2.

#### 4.3 SUPPORT DEPARTMENT SIGNATURES

All signatures must be obtained within 1 day

Upon receipt of the SSI form the Nominated Person will assess which support departments will be involved and who will need to review the study. The application form and study protocol, along with any other relevant documentation will be e-mailed to the POC by the R&D Manager, 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 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 POC.

If any support department(s) raises an objection, and they can not be resolved after discussions have taken place with the R&D Manager, the local CLRN Lead RM&G Manager 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 approval of the study to be given.

In the event of any serious issues concerning the study whereby the Trust is unable to give approval an e-mail detailing the reasons and/or concerns will be sent to the Lead RM&G Manager or CI/PI for non-portfolio studies.

In the event of any issues delaying the approval 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.

#### DIRECTOR SIGNATURES

Upon receipt of the SSI form the Nominated Person will assess which Divisional Directorates will be involved and which Director will need to 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.

The same process for obtaining signatures from support departments will be followed.

The updated Divisional Directorates list is sent by the Medical Directors office on a monthly basis 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.

#### CONTACTS AND SIGNATORIES

There must be 3 POC's and 3 named authorised signatories for 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.

If an unacceptable delay will occur due to absence of the signatories, a decision must be made between the CI/PI, support department and R&D Department on how to issue NHS approval within a suitable timescale.

(Spreadsheet saved in governance/expedited approval)

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 **may** 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.

TURNOVER TIME

R&D approval can only be issued once a favourable opinion from ethics and, if applicable, a notice of acceptance has been received from the MHRA. All governance checks should be carried out as soon any documentation is received so that there is no delay in issuing Trust approval.

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.

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 approval: Director of R&D or Director of Corporate Development

For other responsibilities relating to this SOP: For CLRN portfolio studies – Lead RM&G Manager; For Non CLRN portfolio studies – Commercial Trials Manager

Nominated Person – any R&D Officer

**5. ILLUSTRATIONS/APPENDICES**

*Appendix 1*

*Appendix 2*

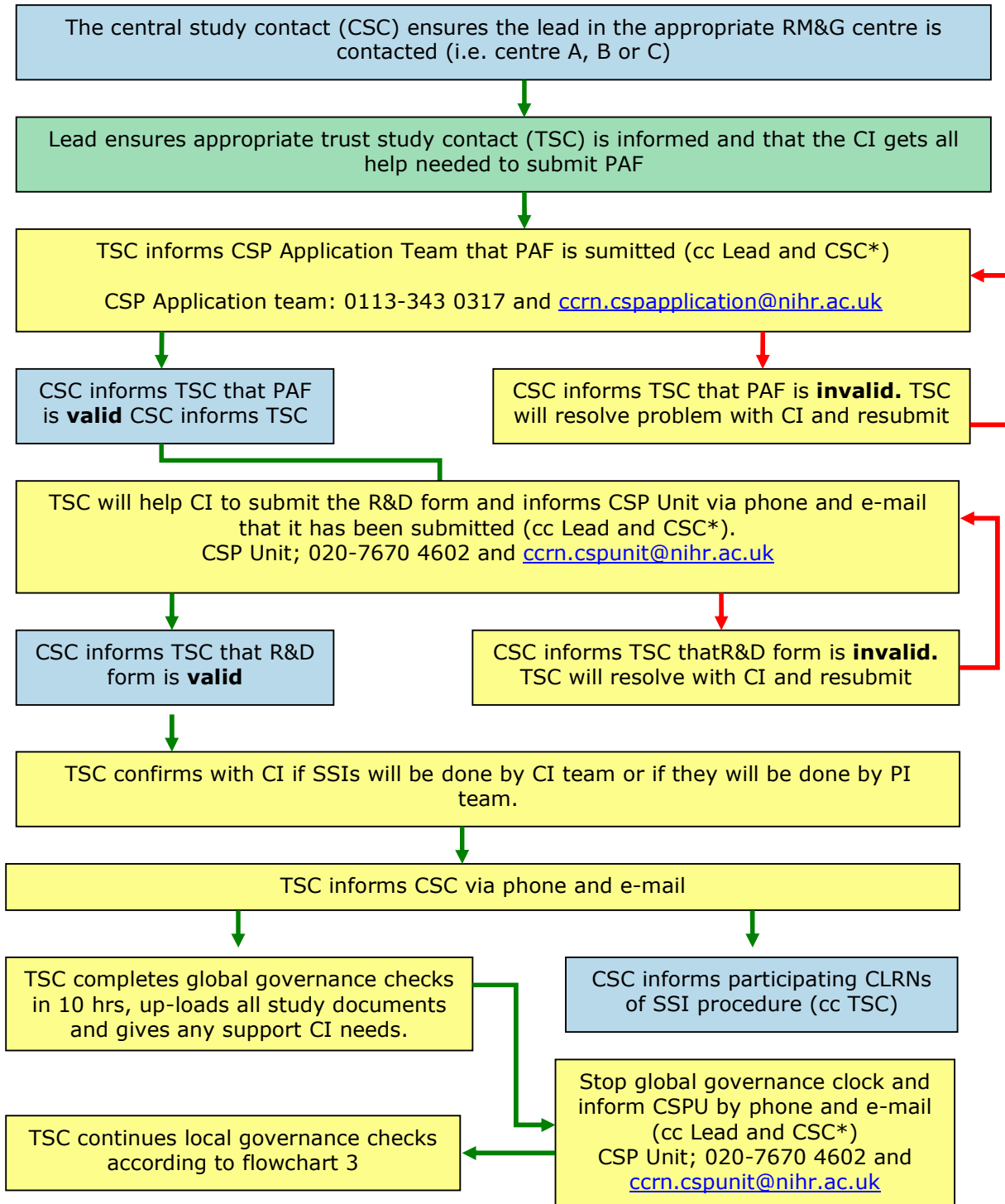
**6. CHANGES SINCE LAST VERSION**

Description of changes
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<i>Section Ref:</i>	<i>Brief description of change</i>

**Appendix 1:**  
**Flowchart 2;** CSP expedited process for Pandemic Flu studies

**Lead CLRN action plan**

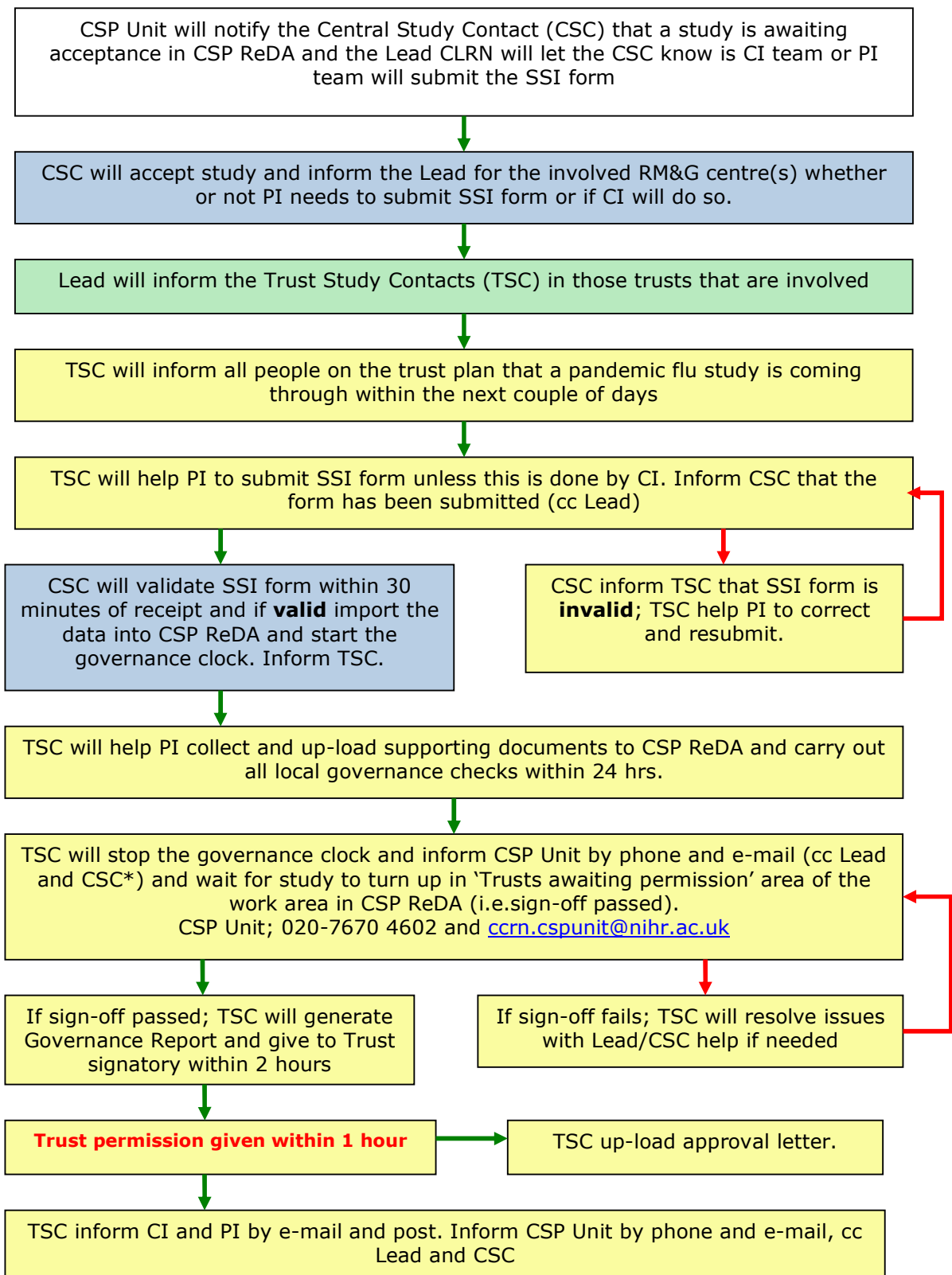


\*Contact details for Lead and CSC in appendix 1

Legend for flowcharts 1 & 2:

- = tasks carried out by central study contact (CSC) or CRN CC
- = tasks carried out by the lead in Centre A, B, or C
- = tasks carried out by the trust study contact (TSC)

**Appendix 2:**  
**Flowchart 3;** CSP expedited process for Pandemic Flu studies  
**CLRN action plan**



\*Contact details for Lead and CSC in appendix 1