# Gaining NHS Trust R&D Approvals

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<tr>
<td>Author:</td>
<td>Claire Daffern, QA Manager</td>
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<tr>
<td>Approved by:</td>
<td>Dr Sarah Duggan, CTU Manager</td>
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## Revision Chronology:

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<thead>
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<th>Version</th>
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<tr>
<td>Version 1.1</td>
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<td>Addition of amendment process via CSP. Web links updated</td>
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Effective: 1 October 2012

Version: 1.1
Gaining NHS Trust R&D Approval

1. Purpose
This Standard Operating Procedure (SOP) describes the process for obtaining permission to set up and run clinical trials within the National Health Service (NHS).

2. Background
Written approval from each NHS organisation is required before research can commence at a particular site. This is in addition to obtaining approval from a Research Ethics Committee (REC) which is detailed in SOP 6 ‘Ethical Approvals and Communications’ and, if applicable, regulatory approval from the Medicines and Healthcare products Regulatory Agency (MHRA), see SOP 5 ‘Regulatory Approvals and Communications’.

As a result of the 2006 Department of Health (DH) research and development strategy; ‘Best Research for Best Health’ a new streamlined system for gaining R&D approval was recommended. From November 2008 the National Institute for Health Research (NIHR) introduced the Coordinated System for gaining NHS Permissions (CSP) for all studies included in the NIHR Portfolio to ensure all quality assurance and statutory requirements in respect of clinical research are met, through standardising and streamlining the process for gaining NHS Permission in England.

NIHR CSP:

- Provides a single point of access and application (via IRAS) for investigators applying for NHS permission, for single site and multi-site studies
- Defines and carries out checks that only need to be done once, and those that are required for each location
- Coordinates the approvals process, resulting in more rapid NHS permission across sites in multi-site studies
- Ensures clarity regarding the roles and responsibilities of sponsors, investigators, Networks and Trusts
- Links with other processes alongside NHS review and permission, including gaining ethics and other regulatory approvals
- Has time targets built into the process.

3. Procedure
3.1 Who?
The Chief Investigator (CI) along with the Principal Investigator (PI) at each site (or their delegate) is responsible for ensuring written permission to commence work at a particular NHS site has been obtained.

3.2 When?
Written approval from the relevant NHS R&D office must be gained prior to any trial specific procedures commencing at that site e.g. patients being approached about the
trial or any Investigational Medicinal Products (if applicable) being delivered to the site.

3.3 How?
Approvals for research in the NHS should be applied for using the Integrated Research Application System (IRAS) accessed via: https://www.myresearchproject.org.uk/
A new project can be set up initially by answering the questions on the Project Filter page.

When you create a new project in IRAS you will also be asked to complete a short CSP Application Form to determine your eligibility for the NIHR Clinical Research Network (CRN) Portfolio. You should receive a response within two working days of submitting the form. If your study is automatically eligible or potentially eligible for the NIHR CRN Portfolio you can then proceed through NIHR CSP.

Further information on the CSP system can be accessed via the UKCRN website: http://www.crncc.nihr.ac.uk/about_us/processes/csp

3.3.1 Portfolio studies
Studies eligible for inclusion in the NIHR CRN Portfolio should use the NIHR CSP system. The Site-Specific Information (SSI) Form contains questions specific to an individual research site and a separate SSI form must be produced via IRAS for each site for assessment by the relevant local R&D office. The SSI form can then be transferred to the Principal Investigator (or their delegate) at each site for completion.

The Chief Investigator (CI) needs to:

- Complete Project Filter on IRAS
- Select England for location of Lead R&D office
- Select Yes for application to be processed through NIHR CSP
- Complete a CSP Application Form within IRAS and submit as per instructions
- Choose relevant Comprehensive Local Research Network (CLRN) linked to the NHS organisation where you’re based
- Complete and submit NHS R&D Form via IRAS (Use the submission checklist on IRAS to ensure all required documents are submitted)
- Send all required documentation to Lead CLRN
- Allow PIs access to SSI.

The Principal Investigators (PI) need to:

- Complete Site Specific Information form (SSI)
- Select local CLRN name
- Submit SSI via IRAS
- Send all required documentation to local CLRN.

The CLRN will work with the CI and the PIs to help put together the documents to support the global and local governance checks.
Once the NIHR CSP governance review has been completed successfully, a governance report will be issued to the NHS host organisation. Within 15 days, the governance report will be reviewed by the NHS signatory and a Letter of Permission will be issued. Research can start at that site when the permission letter is received and all other approvals e.g. Main Ethics, MHRA (if applicable) are in place.

3.3.2 Non-portfolio studies

If your study is not eligible for inclusion in the NIHR CRN Portfolio, then you should submit the Site Specific Information (SSI) form directly to the individual R&D office. To do this, you should return to IRAS:

- Select the Project Filter link (at the top left-hand menu)
- Scroll down to question 5a and click NO
- Click the Navigate button at the bottom of the page. The CSP Application Form is removed from the project Forms list. For instructions on how to proceed, refer to the notes on the Submission tab in the NHS R&D Form area
- Your CLRN will be able to advise you on the next steps

For non-portfolio trials, the SSI form is submitted directly to the local R&D office along with all study documents required as per local R&D procedures. The individual Trust’s R&D office will issue an approval letter once all their checks are complete.

NB. A signed copy of the SSI form should also be forwarded to the coordinating centre for filing in the Trial Master File (TMF).

The flowchart below explains the process:
NIHR CSP Flowchart

Chief Investigator (CI) decides to submit study via NIHR CSP

CI logs onto IRAS and completes filter questions as applicable, including:
- Q3a – Select England (enables question 5a)
- Q5a – Select YES for application to be processed through NIHR CSP

CI completes the CSP Application Form – located in the Project Forms list in the left navigation bar

CI submits the CSP Application Form electronically via the Submission tab

CSP Application Form sent to CSP Application Team for review

Study not processed through CSP. Contact Individual Trusts involved in research for further guidance

Study adopted

Yes

CI completes the NHS R&D form and submits it via IRAS once the funding is secured

NHS R&D form validated

CI emails required study documentation to Lead CLRN (as identified on the CSP Application Form)

Global governance checks undertaken*

The part of the process that is relevant to Principal Investigators (participating in multi-centre studies) is represented by green boxes.

* Global governance checks are undertaken once per study (e.g. sponsorship arrangements in place)

** Local governance checks are undertaken for each participating NHS organisation (e.g. whether the pharmacy department can undertake the study)

CI adds SSI form(s) for each participating Trust and transfers the form(s) to Principal Investigators (PIs) in IRAS

CI and PIs complete the SSI for their Trust and submit it via IRAS

SSI form validated

CI and PIs email required local documentation to their CLRN

Local governance checks undertaken**

All checks completed

Quality Assurance performed

Governance Report produced for each Trust. CI/PI informed of completion of governance checks

Trust grants NHS Permission. CI/PI receive Permission letter. Study begins at that Trust.

Target 2 working days

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3.3.3 Amendment process via CSP
Amendments which affect NHS organisations must be notified so sites are aware of any implications in order to implement them promptly and manage the changes.

The facility to process amendments through NIHR CSP is only available to:
- studies which gained NHS Permission via NIHR CSP in the first instance
- studies currently progressing through NIHR CSP.

Substantial and non-substantial amendments are handled in the same way, for more details please see the guidelines produced by NIHR: [http://www.crncc.nihr.ac.uk/about_us/processes/csp/resources/](http://www.crncc.nihr.ac.uk/about_us/processes/csp/resources/)

The CI (or delegate) is responsible for preparing the Notification of Amendment form and submitting the required documentation to the main REC and/or MHRA and to the lead CLRN. It is recommended that the submission of forms to all relevant bodies is done in parallel.

The lead CLRN will check the amendment documents and inform all participating CLRN. The CI retains responsibility for alerting all investigators at site(s) of the amendment and providing them with the relevant documents.

When REC/MHRA approvals are obtained, the CI (or delegate) sends these to the lead CLRN who will notify the participating CLRN. Participating NHS Trust offices may then issue a ‘Notification of continued NHS permission’ letter to the CI.

NHS Trusts have a maximum of 35 days after the submission of an amendment to raise objections otherwise the amendment can be implemented subject to regulatory approval. The 35 day timeline starts on submission of a complete amendment application.

No amendment, other than a safety amendment, may be implemented until the applicable regulatory approvals are in place.

If an amendment is not locally feasible for a participating NHS organisation, they will send a letter of objection to the PI, copying in the CI and local CLRN. If an amendment cannot be approved by an NHS organisation, the research will normally have to be terminated at that site.

3.3.4 Amendment process for non-portfolio trials
For trials not using the CSP system, amendments should be submitted to the main REC and/or MHRA using the standard system; details are provided in SOPs 5 and 6.

List of Abbreviations:
- CI: Chief Investigator
- CLRN: Comprehensive Local Research Network
- CRN: Clinical Research Network
CSP     Coordinated System for gaining NHS Permission
DH      Department of Health
IRAS    Integrated Research Application System
MHRA    Medicines and Healthcare products Regulatory Agency
NIHR    National Institute for Health Research
NHS     National Health Service
PI      Principal Investigator
REC     Research Ethics Committee
R&D     Research and Development
SSI form Site Specific Information form
UKCRN   United Kingdom Clinical Research Network