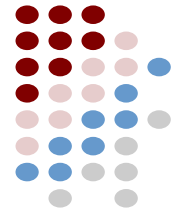


NIHR CSP Factsheet



Version 1.0 November 2008

Important changes for researchers from 18th November 2008

NIHR CSP is being introduced in the NHS in England from **18 November 2008** for NIHR Clinical Research Network Portfolio studies.

All NHS Trusts in Northumberland, Tyne and Wear Comprehensive Local Research Network will go 'live' on 18th November.

Applications for approval using the new CSP system must be made via IRAS.

Studies already submitted for NHS ethical review via the NRES online application should continue to seek permission from the NHS Trusts involved.

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What is NIHR CSP?

The **National Institute for Health Research Coordinated System for gaining NHS Permission (NIHR CSP)** is a system for gaining permission from NHS organisations to undertake clinical research.

The new system will:

- **Reduce the duplication** in the NHS review process
- **Provide a single point** to which sponsors and investigators need to apply for NHS permission to start multi-site and single site studies
- **Ensure clarity regarding the roles and responsibilities** of sponsors, investigators, Clinical Research Networks and NHS Trusts
- Initially be available to studies that are eligible for the NIHR Clinical Research Network Portfolio

What are the benefits of CSP?

NIHR CSP will bring significant benefits, including:

- **Reduced time to gain approvals** across NHS sites
- **Single point of entry** for approvals
- **Standardised process** by which investigators gain NHS permission
- **Reduced bureaucratic burden** particularly for multi-site studies
- **Single national system** that fully satisfies all governance and regulatory requirements
- **High quality process** coordinated nationally through the NIHR CSP Unit and locally through CLRNs





How will CSP work?

NIHR CSP builds on best governance practice being used in the NHS R&D management community. CSP will improve the approvals process by:

- Establishing time targets for key stages.
- Defining checks that only need to be done once across all NHS sites.
- Reducing the administrative burden on researchers.
- Ensuring that researchers obtain all the necessary approvals prior to commencement of their study.

Eligibility for NIHR CSP

The NIHR Portfolio Team will make a decision within 3 days of submission as to whether a study is potentially eligible or not eligible. If the study is automatically eligible or potentially eligible for the NIHR Clinical Research Network Portfolio, the study details will be transferred to the CSP system (CSP ReDA) from IRAS and processed through NIHR CSP.

Potentially eligible studies will be further assessed over a 30-day period after which a decision is made on whether the study is adopted onto the Portfolio.

For studies not eligible for the Portfolio, NIHR CSP is not available. NHS Permission should be sought by contacting each NHS organisation participating in the research.

http://www.ukcrn.org.uk/index/clinical/portfolio_new.html

Submitting to NIHR CSP through IRAS

CSP is accessed by investigators through the **Integrated Research Application System (IRAS)**. See flowchart 1 and 2

Chief Investigator:

- 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 **Portfolio Adoption Form (PAF)** within IRAS and submit PAF for consideration of eligibility for the NIHR Clinical Research Network Portfolio
- Complete and submit **NHS R&D Form** via IRAS
- Send all required documentation to the Lead CLRN
- Allow PIs access to SSI.

Principal Investigators:

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

<https://www.myresearchproject.org.uk/>

Research governance checks

Staff based within the CSP Unit in London, the 25 CLRNs and NHS Trusts will undertake a standard set of checks to ensure that studies meet the requirements of the Research Governance Framework and all applicable regulations.

A Lead CLRN is selected to work with the Chief Investigator (CI) to undertake checks for the study across all sites. In Northumberland, Tyne and Wear CLRN, the Core Team will contact the CI to request a copy of the funding approval letter and assess the completeness of documents submitted via IRAS. Once the CLRN have validated the application, a Lead Trust will be selected to work with the CI to undertake the global checks not already carried out by the CSP Unit.

The CLRN will assess incoming SSI forms from local Principal Investigators (PI) for completeness and notify local Trust staff once validated. Participating Trust R&D staff will work with their local PI to undertake the remaining governance checks.

<http://www.ukcrn.org.uk/index/clinical/csp/apply/investigators.html>

Study sign off in CSP

Once all checks have been undertaken by the CSP Unit, the Lead CLRN and the Trust, the process is checked (Quality Assurance) and signed off within the CSP system. A **21 day clock** then starts, during which a governance report is printed from the system and the local Permission Signatory for the Trust gives approval.

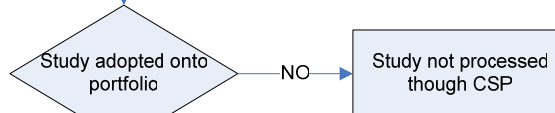
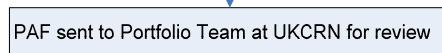
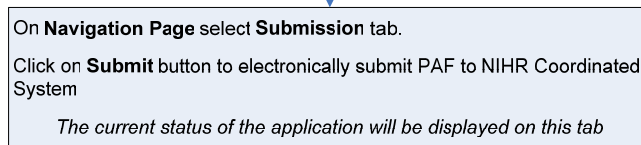
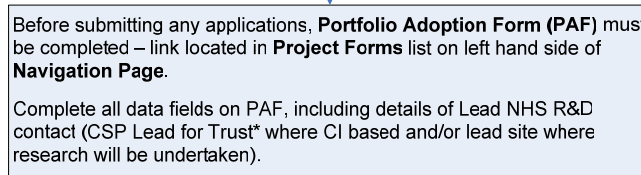
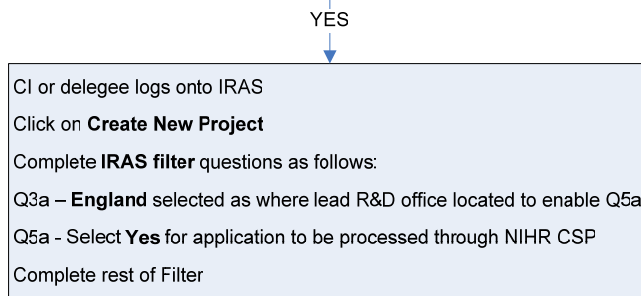
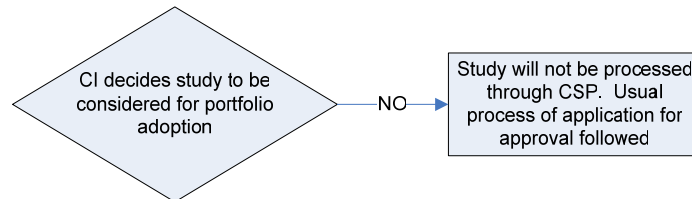
Once the letter of approval has been received and logged on the CSP system, the study can start in that Trust. The CI and PI will be informed that the study has been approved by email.



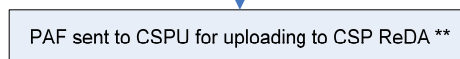
CSP Investigator Flowchart 1

– Submission for Portfolio Adoption and Entry onto CSP ReDA

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POTENTIALLY



Timelines for Adoption

The Portfolio Team have 2 working days to decide if studies are **potentially eligible** or **not eligible**.

The Portfolio Team then have a further 30 days to review studies to decide if potentially eligible studies are to be adopted.

Studies that are not adopted will be processed through CSP until the point at which they decide that the study is not eligible. At this point, the usual process for gaining permission should be followed.

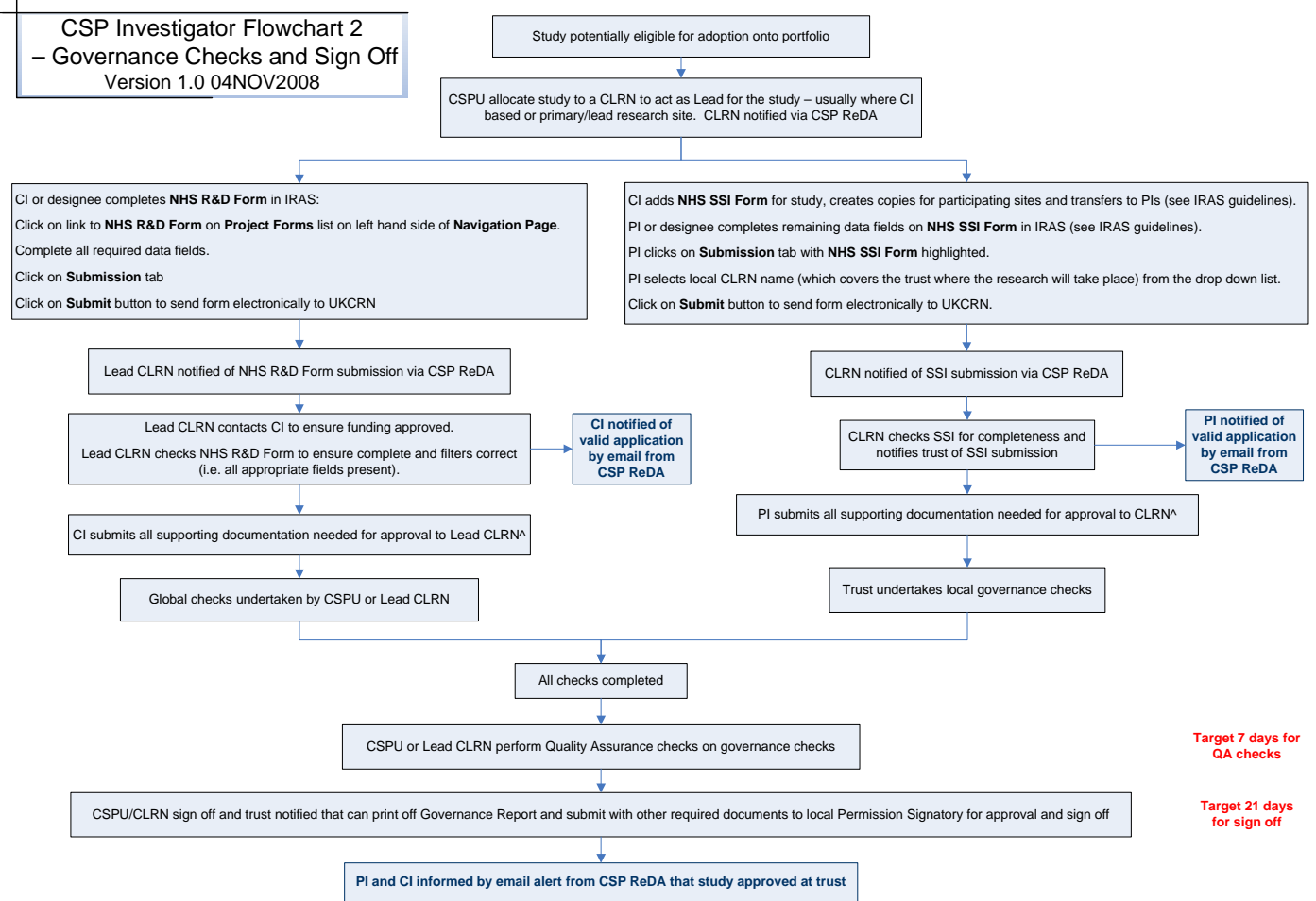
KEY

* Details of CSP Lead for NTW CLRN Trusts can be found on: <http://www.ukcrn.org.uk/index/networks/comprehensive/clrns/northumberland.html>

** CSP ReDA is the system which tracks the CSP process

CSPU – CSP Unit, part of UKCRN, based in London

CLRN – Comprehensive Local Research Network



Target 7 days for QA checks

Target 21 days for sign off

^ NTW CLRN email address: tnu-tr.ntw-clrn@nhs.net

Further information links

Northumberland, Tyne and Wear Comprehensive Local Research Network

<http://ntw-clrn.ukcrn.org.uk>

NIHR Clinical Research Network Portfolio

http://www.ukcrn.org.uk/index/clinical/portfolio_new.html

NIHR CSP

<http://www.ukcrn.org.uk/index/clinical/csp.html>

IRAS/Ethics

<https://www.myresearchproject.org.uk/>

<http://www.nres.npsa.nhs.uk/applicants/>

CSP contact details and query service

Local CSP Leads

CSP Leads and support staff in each local trust are available to answer queries from local investigators on CSP and to provide updates on how studies are progressing through the approval process. The CSP staff within trusts will liaise with local clinical service departments (e.g. pharmacy, radiology, laboratories) to gain approval or to resolve any study issues. Contact details are available on: <http://ntw-clrn.ukcrn.org.uk>

NTW CLRN

CSP Document Submission

Email: tnu-tr.ntw-clrn@nhs.net

CSP Lead

Justine Smith

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