



NIHR Coordinated System for gaining NHS Permission (NIHR CSP)

Mary Cubitt

NIHR CRN CC



Outline

- Overview of CSP
 - What CSP aims to achieve
 - Outline of how CSP operates
 - CSP communication pathways
 - CSP timelines
 - Commercial studies
 - Amendments
 - Future developments
- Other advance questions



NIHR CSP

NIHR Coordinated System for gaining NHS Permission

Gaining NHS Permission for research

- Research Governance Framework - need permission from NHS organisation
- Not one NHS – approx 400 NHS organisations
- All different application systems
- All undertake different reviews
- For research team difficult to manage for multicentre studies

NIHR CSP - aims

- Single point of entry for NHS Permission
- Make NHS research governance review consistent, transparent and predictable
- Proportionate review based on study type
- Reduce duplication
- Consistent timelines across sites
- Reduce overall timelines
- Greatest value for multicentre sites

NIHR CSP – principles 1

- Obtaining NHS Permission is actively facilitated in as timely a manner as is possible
- NHS R&D review is consistent across sites
- NHS Permission is not given until all regulatory approvals are in place
- NIHR CSP depends on researchers and/or sponsors submitting supporting documents in a timely manner
- NIHR CSP depends on timely negotiation of costs and contracts/agreements

NIHR CSP – principles 2

- Study wide (global) information is submitted once and shared across all participating sites
- Study wide (global) governance checks are done once and only once
- Outcome of study wide (global) governance checks shared across all participating sites
- Local information is supplied for each site
- Local governance checks are undertaken for each site

NIHR CSP – a conduit

- CSP cannot give one NHS Permission for all sites
- Each site is a separate legal entity
- Each site has to issue its own permission
- CSP provides the evidence on which that permission is based
- CLRN fund staff to deliver CSP processes – some based in CLRNs, most based in NHS R&D Offices
- For studies adopted to NIHR Clinical Research Network Portfolio and BRUs, BRCs and CLAHRCs

NIHR CSP - implementation

- NIHR CSP went live 18th Nov 2008 – updates ongoing to improve
- Hub of system is NIHR Clinical Research Network Coordinating Centre
- Spokes are 25 Comprehensive Local Research Networks (CLRNs)
- CLRNs resource R&D staff – sometimes centrally in CLRN most often hosted by NHS R&D Offices
- System requires close working with NHS R&D

Using CSP

- Sponsor/investigator/study coordinator discusses possible adoption with networks
 - Commercial
 - Topic Specific
 - CLRN
 - CSP Application Form in IRAS
- Complete IRAS dataset
 - Filter 3a and 5a
- Submit R&D Form electronically from IRAS to CSP
- Email supporting documents to Lead CLRN

Using CSP 2

- Lead CLRN funded RM&G staff work to complete global checks – including recording REC and regulatory approvals
- In parallel submit SSI form for each site electronically from IRAS to CSP
- Email local supporting documents
- Sponsor/CI informed when global checks complete
- As permission is gained at each site sponsor/CI informed

IRAS

www.myresearchproject.org.uk Contact: IRAS Helpdesk or CSP Helpdesk

Create project dataset

Submit Research Ethics Committee Form

Submit MHRA Form (and/or other regulatory submissions)

Submit CSP Application Form

Submit R&D Form

Submit SSI Forms

ADOPTION

Network adoption can be initiated before IRAS submission

Submit to Network:

- Study protocol
- Feasibility and Adoption Submission Form
- Industry Costing Template

Undergo adoption process to NIHR CRN Portfolio including feasibility and site selection (max. six weeks)

For each participating site: Negotiate and agree contract and costs with support from Networks (using Industry Costing Template)

Contact: Nominated contact from local research Network

Contact: Industry Liaison Manager from relevant Network Coordinating Centre

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Contact: Nominated contact in Lead CLRN

Send 'global' supporting documents to Lead CLRN for standardised study-wide governance checks carried out and shared across all participating sites

For each participating site: Send 'local' supporting documents to participating CLRNs for standardised local governance checks to be carried out

For each participating NHS organisation: Governance Report with evidence of completed Global and Local checks issued

Approvals granted from MHRA and other regulatory bodies

REC approval granted pending NHS permission

For each participating site:
NHS permission letter
Research can start at a site when the permission letter is received from that NHS organisation

Communication flow within CSP

- Sponsor contact links with Lead CLRN study contact re all NHS Permission issues
- Lead CLRN links with CSP Unit and reports to Sponsor Contact
- CSP Unit is in regular contact with Participating CLRNs in order to report to Lead CLRN
- Each Participating CLRN should have a site specific study contact

What can an investigator expect from NIHR CSP?

- A Lead CLRN study contact to provide support and ongoing updates
- That governance queries from NHS sites are channelled through Lead CLRN
- That the study will progress in a timely manner as information is received
- Information is held confidentially and only those involved in the NHS Permission process will have access
- That the checks undertaken are consistent across sites

What does CSP expects from investigators/sponsors?

- Agreement with Lead CLRN regarding frequency of update across sites
- Use Lead CLRN contact as point of contact for NHS Permission queries
- All queries resolved as soon as possible
- All documents supplied as soon as possible
- Unmodified Model Agreements used where applicable or other arrangements as required

CSP timelines

- 3 working days to validate forms
- 7 days to quality assure governance checks
- 21 days from issue of governance report to Trust issuing NHS Permission letter

- Not yet national targets for whole process – so interdependent on things outside of CSP control
- Working towards agreement on these

Commercial studies

- Adoption process to networks is different to non commercial studies
- Network Industry Managers give extra support
- Use of CSP is the same – main communication is with sponsor contact not Chief Investigator



Clinical Trials Units

- Same communication pathways but with CTU contact not Chief Investigator
- Need to make this clear in IRAS application

Amendments

- Protocol amendments are messy but essential part of ongoing study management
- CSP initially implemented without facility
- Amendments treated on ad hoc basis before formalised process introduced to CSP in Sept 2009
- Currently working on a better way of handling amendments to get consistency across NHS organisations while not making overly burdensome
- Will address issue of which amendment referred to
- Release expected in Feb 2010

Future developments

- CSP process continues to develop
 - Process flows for study types
 - Governance checks
 - Amendments
- Enabling support technology continues to develop
 - RDMIS will be the next big change
- Develop to support the Research Support Services SOPs

Other questions

- CSP ReDA – training provided by CLRN Lead RM&G Manager locally for those with user IDs
- Support costs – not a proportion just what is needed to support study in NHS. Agreed with CLRN.
- Acceptance of global checks – undertaken by CLRN or R&D staff of lead NHS Trust. In many areas accepted but still working on being accepted in a few

Other questions 2

- The only documents that should need to be submitted to support an SSI Form are
 - Local research team CVs and evidence of appropriate training
 - PIS & consent form with local details/heading where appropriate
 - Internal authorisations – local agreement to format
 - PI signature on IRAS declaration page
 - All other available on CSP ReDA via local CLRN



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NIHR CRN CC

CSP Helpdesk

crncc.csp@nihr.ac.uk