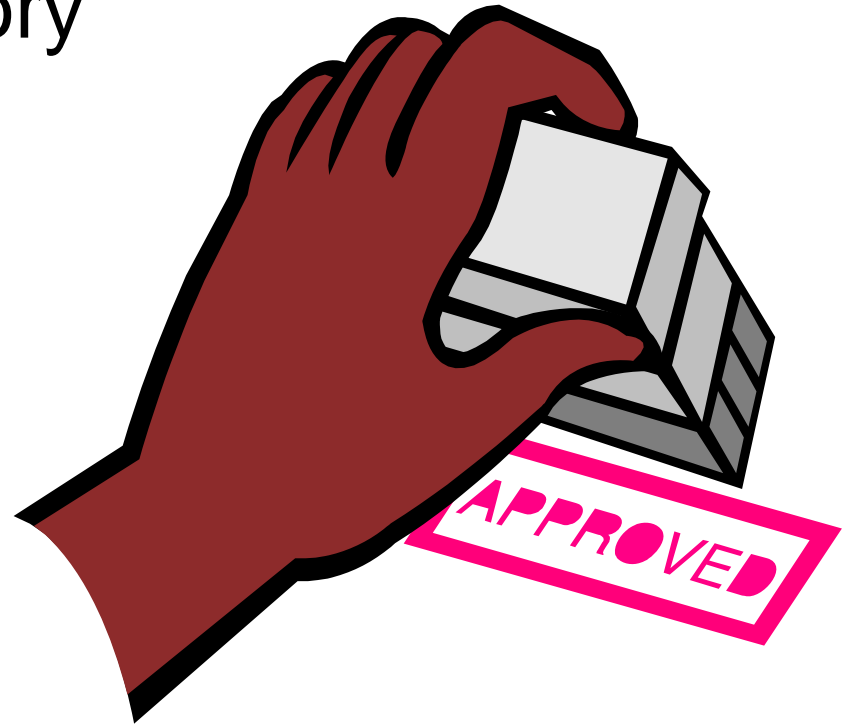


Removing the barriers – integration and networking

Ruth Hulbert
Lead RM&G Manager
Kent & Medway CLRN

Research in the NHS

- Approval – Regulatory
- Approval – Ethics
- Permission – NHS



Context

- Bottle-necks and barriers
 - Lack of consistency and duplication
 - Variation in interpretation and processes
- Key areas:
 - Duplication in applications
 - Delays and duplication in honorary contracts
 - Delays in negotiation of contracts
 - Variation in interpretation
 - Variation and duplication in NHS permissions

Streamlining NHS Permission

- IRAS – reduces duplication in form filling
- CSP – one application point for NHS permission, consistent review
- Research Passports – clarifies the HR arrangements for researchers working across NHS Trusts
- Contracting – model agreements (with costing template for industry studies)
- R&G Advice Service
- Research Support Services – harmonises and streamlines local NHS R&D processes



NHS

*National Institute for
Health Research*

IRAS



IRAS

INTEGRATED RESEARCH
APPLICATION SYSTEM

Integrated Research Application System

- Captures information needed for the relevant permissions and approvals for health and social care / community care research in the UK.
- Uses filters to ensure required data is collected and collated appropriately based on:
 - Type of study
 - Approvals/permissions required.
- Consultation in use Jan-Jul 08
- Compulsory for NHS R&D from 1st April 2009.

Applications Included in IRAS

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Gene Therapy Advisory Committee (GTAC)
- Medicines and Healthcare products Regulatory Agency (MHRA) – Medicines and Devices
- Ministry of Justice
- NHS / HSC research offices
- NRES/ NHS / HSC Research Ethics Committees
- National Information Governance Board (NIGB) [formerly PIAG]

IRAS Format

- Web-based system
 - www.myresearchproject.org.uk
 - Requires user account
 - Help section
- Single integrated dataset
 - Filter selects appropriate questions
 - Questions grouped to create application forms
- No duplication of information

Creating an account/logging in

Integrated Research Application System - Windows Internet Explorer
https://www.myresearchproject.org.uk/irascsp/Signin.aspx

File Edit View Favorites Tools Help

Integrated Research Application System

HOME | **LOGIN** | **CREATE ACCOUNT** | HELP | CONTACT US

IRAS
INTEGRATED RESEARCH APPLICATION SYSTEM

Welcome to the Integrated Research Application System (IRAS)

The Integrated Research Application System (IRAS):

- Is a single system for applying for the permissions and approvals for health and social care / community care research in the UK
- Enables you to enter the information about your project once instead of duplicating information in separate application forms
- Uses filters to ensure that the data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required
- Helps you to meet regulatory and governance requirements
- Retains familiar aspects of the NRES form system

The [consultation-in-use](#) phase of IRAS ran from January to June 2008. This phase has now closed. Thank you to the many of you who took the time to give feedback on IRAS. Many of the suggestions received will be or have already been incorporated into IRAS.

IRAS captures the information needed for the relevant approvals from the following review bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Gene Therapy Advisory Committee (GTAC)
- Medicines and Healthcare products Regulatory Agency (MHRA)

Please Login

If you are a first time user of the Integrated Research Application System please read the information on the [help page](#) before you proceed to login.

Login:
(Your full e-mail address)

Password:

Forgotten Password? [Click here](#)

* Passwords are case sensitive.

Create new project and help

Integrated Research Application System - Windows Internet Explorer

https://www.myresearchproject.org.uk/Forms/MainFormList.aspx

Integrated Research Application System

HOME | MY PROJECTS | MY CONTACTS | MY ACCOUNT | LOGOUT | HELP | CONTACT US | E-LEARNING

IRAS
INTEGRATED RESEARCH APPLICATION SYSTEM

My Projects

Project Categories
[Manage Project Categories](#)

New Project
Create new IRAS Project

New Minimal Dataset
Create minimal dataset for old NRES Form project

Import
Import IRAS or EudraCT Form XML

Projects | Requests for Authorisation

Project Title	Created On	Status	Action
---------------	------------	--------	--------

Project Filter

[HOME](#) | [MY PROJECTS](#) | [MY CONTACTS](#) | [MY ACCOUNT](#) | [E-LEARNING](#) | [HELP](#) | [CONTACT US](#) | [LOGOUT](#)

Project Title: **Acetaminophen Dosage in Neonatal Ischaemic Syndrome (ADONIS)**

Section:

Application to:

[NAVIGATE](#) [PRINT](#) i

[SAVE NOW](#) [UNDO CHANGES](#)

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

On-line guidance is available wherever you see a hyperlinked word or this symbol displayed i. Please read this guidance carefully. For Help with your application, click [here](#).

Please enter a short title for this project (maximum 70 characters) i

Acetaminophen Dosage in Neonatal Ischaemic Syndrome (ADONIS)

1. Is your project research? i

Yes No

IRAS – project filter

- Short list of questions about the project
- Dynamic – subsequent filter questions may alter depending on responses
- Generates project dataset questions and application forms required for study type
- Answer all the questions carefully and refer to question specific guidance as necessary

CSP entry questions – Q3 & 5

3. In which countries of the UK will the research sites be located?(Tick all that apply)

- England
- Scotland
- Wales
- Northern Ireland

3a. In which country of the UK will the lead R&D office be located?

- England
- Scotland
- Wales
- Northern Ireland

5. Will any research sites in this study be NHS organisations?


- Yes No

5a. Do you want your NHS R&D application(s) to be processed through the NIHR Coordinated System for gaining NHS Permission?

- Yes No

If yes, you must complete and submit the Portfolio Adoption Form immediately after completing this project filter, before proceeding with completing and submitting other applications.

Forms and question range



HOME | MY PROJECTS | MY CONTACTS | MY ACCOUNT | LOGOUT | HELP | CONTACT US | E-LEARNING

Navigation Page

Project Title: **Acetaminophen Dosage in Neonatal Ischaemic Syndrome (ADONIS)**
 Project Type: **Clinical trial of an investigational medicinal product**
 Full project dataset

Project Filter

[Click here to go directly to the Project Filter questions](#)

Full Set of Project Data

[Click here to access the integrated dataset for all project forms](#)

Project Forms

[NIHR CSP Application Form](#)

[NHS/HSC R&D Form \(project information\)](#)

[MHRA Medicines \(EudraCT application form\)](#)

Site-specific Forms i

No SSI Forms created yet.

Navigate
Save/Print
Manage
Transfer

Project Form Navigation

[Print blank reference only PDF for the full project dataset](#)

Status enabled disabled

SECTION	QUESTION RANGE					
Part A	A1	A2	A3	A4-A5	A6	A7-A9
	A10-A13	A14	A15-A17	A18	A19	A20-A22
	A23-A26	A27	A28-A30	A31-A34	A35	A36-A38
	A39	A40-A42	A43-A45	A46-A49	A50-A53	A54-A57
	A58-A62	A63-A64	A65-A69	A70-A72	A73-A75	A76-A79
	A80					
Part B Section 1	1-2	3-5	IMPs	13	14-15	16
	17-19	20-22	23	24	25-28	29

Form submission

Project Filter
Click here to go directly to the Project Filter questions
Full Set of Project Data
Click here to access the integrated dataset for all project forms
Project Forms
NIHR CSP Application Form
NHS/HSC R&D Form (project information)
MHRA Medicines (EudraCT application form)
Site-specific Forms ⓘ
No SSI Forms created yet.

Navigate Save/Print Submission Transfer
Electronic Submission To NIHR Coordinated System
<p>A Lead Comprehensive Local Research Network (CLRN) will support you through the process of obtaining NHS permission via NIHR CSP.</p> <p>Before submitting your NIHR CSP Application Form, you should choose the CLRN that covers the area where your study's Chief Investigator is based.</p> <p>Please select the appropriate CLRN from the drop-down list. More information on identifying the correct CLRN can be found on the NIHR Clinical Research Network Coordinating Centre website.</p> <p><input type="text" value="Birmingham and the Black Country"/></p> <p>Please click on the "Submit" button below to send your NIHR CSP Application Form Form electronically to UKCRN. UKCRN will assess the eligibility of your study for inclusion in the NIHR Portfolio. Your form will have a submission code. Once you have submitted the form this version will be listed in a submission history below. You can save or print the version submitted by clicking on the print button next to the version below. This will create a pdf file of your form that you can save to your computer and/or print. For information about applying for R&D review in Scotland, see http://www.rdforum.nhs.uk/links.</p> <p><input type="button" value="SUBMIT"/></p> <p>If you have submitted in error or made a mistake on your application, and your application has not yet been processed by UKCRN then you should see a "Recall" button below. You can recall your last submission by clicking this button. If your submission has already been processed, you will see the "Submit" button. If you need to amend your NIHR CSP Application Form before you submit the R&D Form, you must re-submit your amended form. Please click on the "Submit" button to send your amended NIHR CSP Application Form Form electronically to UKCRN. For information about applying for R&D review in Scotland, see http://www.rdforum.nhs.uk/links.</p> <p><input type="button" value="Recall"/></p>
Submission history

Using IRAS to make your applications

- Whenever possible, complete the integrated dataset NOT individual forms
- Use IRAS to enter information, but submit application forms to each individual review body separately
- Each review body has different submission requirements
- Each application will need to be signed or authorised. Electronic authorisation can be used for study-wide forms.

Submitting applications

- Select the appropriate form on the navigation page and then select the submission tab for specific guidance
- To print a hard copy for submitting follow instructions on submission tab and create submission code
- If you print from other areas of IRAS it will say “Draft”
- Each form has a checklist of documents to accompany the application
- Tracking submissions – each submission has a code and is recorded in an audit trail
- Please enable pop-ups on your computer!

Useful functions in IRAS

- CV template
- Personal address book
 - Access via green icon
 - Add details entered into forms using blue icon
- Contacts for review bodies
- Blank application forms and examples
- E-learning module

Tips for preparing applications

1. Complete project filter to find out which applications to make
2. Print off blank integrated dataset to find out what information you need to gather
3. Find out who will need to authorise your forms and check if you can use electronic authorisation (they need an IRAS account)
4. Print off checklists and gather documents for applications

Coordinated System for Gaining NHS Permission (NIHR CSP)



What is NIHR CSP?

- A consistent, quality assured & standardised process for gaining NHS permission
- Single application point through IRAS
- Multi-centre & single site studies
- Managed nationally by CSP Unit & CLRNs
- Coordinated approach with local input

Who is CSP for?

- Initially only for studies eligible for NIHR CRN Portfolio
- Can be used for UK-wide studies – compatible with similar systems in devolved nations

NIHR CSP Benefits

- **Consistency** – consistent and comprehensive set of NHS research governance checks
- **Speed** – streamlining and rationalising processes to reduce NHS R&D approval times
- **Predictability** – a single system for processing and reviewing applications for NHS permission, centrally coordinated and supported through NIHR Comprehensive Local Research Networks

How Does CSP Work? (1)

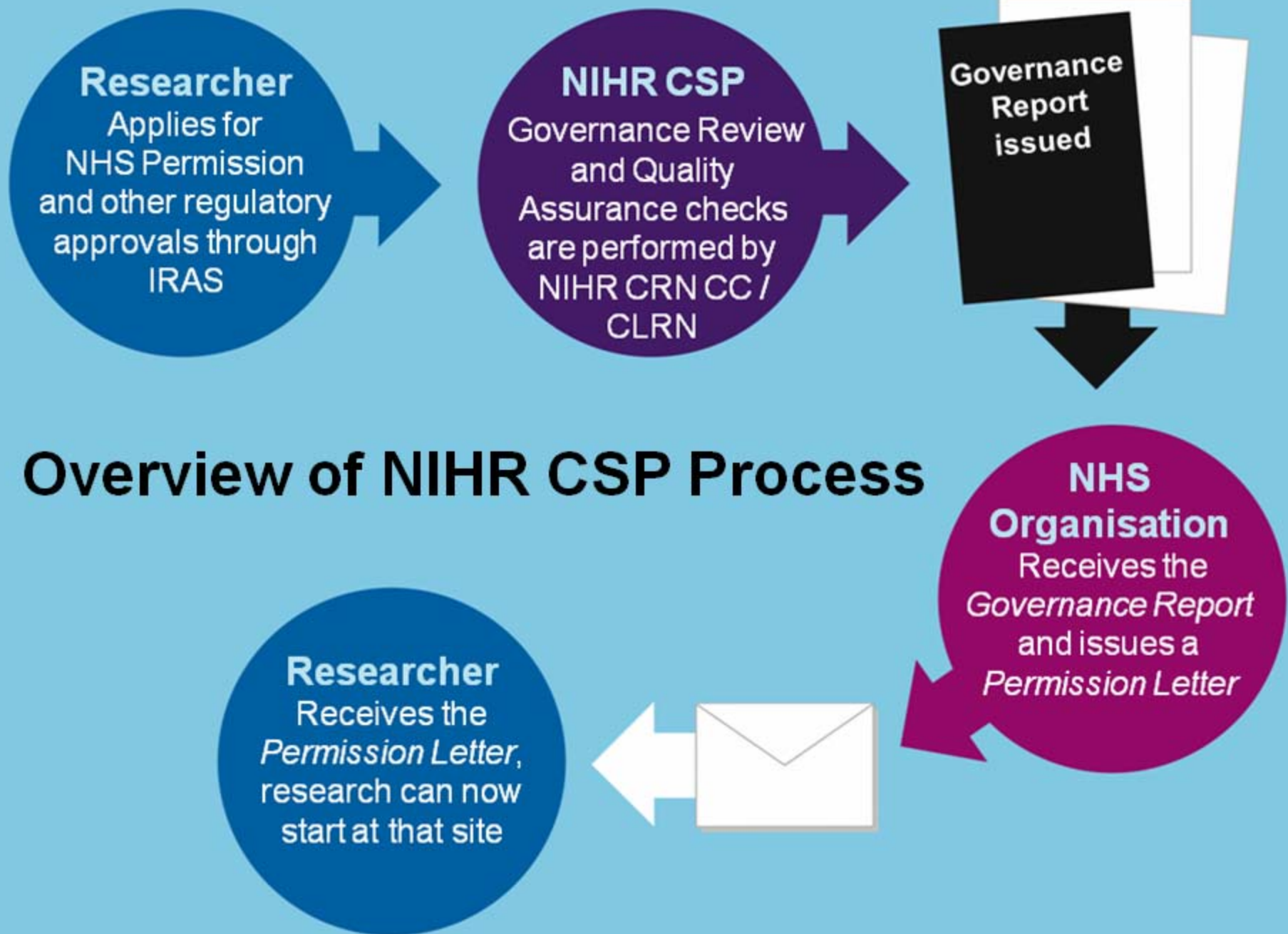
- All instructions and submissions through IRAS
- CI submits CSP Application Form to NIHR via IRAS
 - 2 days to let you know if potentially eligible
 - 30 calendar days to assess for adoption
- CI submits R&D Form to CSP via IRAS
 - Once emailed to say potentially eligible, can submit R&D Form
 - Form is reviewed and if validated is imported into CSP ReDA
 - If not validated, reasons why will be sent to CI (cc'd to Coordinator if listed on R&D Form)

How Does CSP Work? (2)

- CI emails documents to Lead CLRN
- Lead CLRN does global governance checks
- PI submits SSI form to CSP via IRAS
 - Can only submit once R&D Form validated and imported
 - 1 per NHS Trust/ PCT
- PI emails local study documents to local CLRN
- Local CLRN does local governance checks

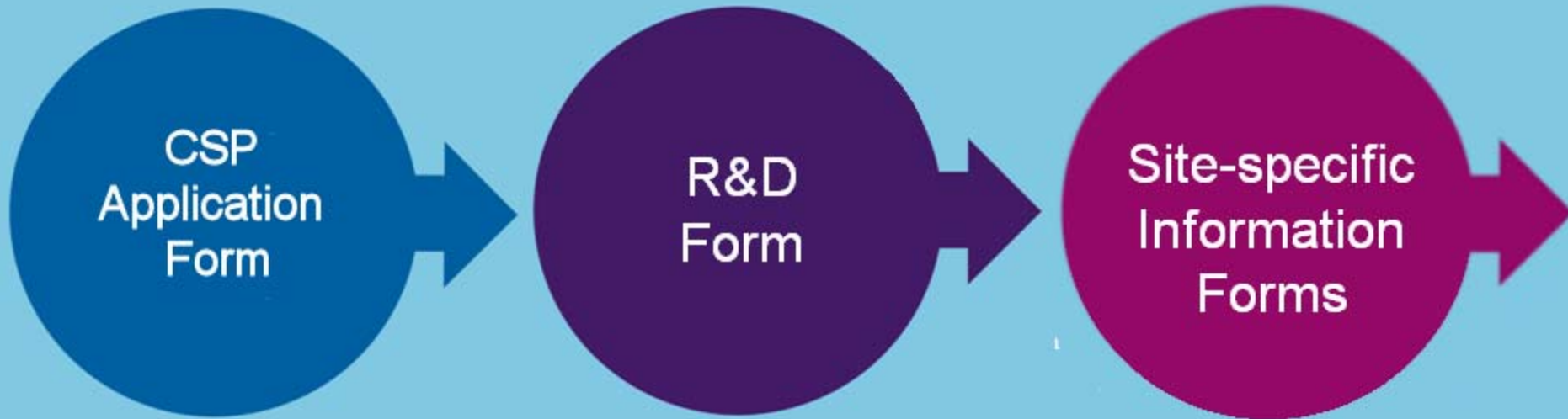
How does CSP Work? (3)

- When checks complete for a site, Governance Report generated
- Trust uses evidence in Governance Report to issue permission letter
- Study begins at each site in turn



Overview of NIHR CSP Process

Submission of Forms from IRAS to CSP



- Assess eligibility
- Early advice

- Global checks (CSPU and Lead CLRN)
- Confirm eligibility

- Local checks (Local CLRN)

What are the Governance Checks?

- Depends on type of study
 - Uses IRAS filter – so essential it is correct
- Global checks
 - Ethics Approval
 - MHRA
 - Sponsor insurance/ indemnity
- Local Checks
 - Local team's CVs & training appropriate
 - Resources available

Summary

- Global checks based on the R&D Form with study-wide documents done only once
- Local checks based on the SSI Form with local documents done for each site
- Each site does not repeat global checks so subsequent sites can be set up quicker
- No need to send all documents to every site
- Checks standardised and consistent

Contacts

IRAS Helpdesk: iras@nres.npsa.nhs.uk

IRAS Technical Helpdesk: helpdesk@infonetica.net

CSP Helpdesk: crncc.csp@nihr.ac.uk

Links

IRAS: www.myresearchproject.org.uk

NIHR CSP: <http://www.crncc.nihr.ac.uk/index/clinical/csp.html>

Passports, model agreements and advice

Streamlining honorary contracts

- Research Passport
 - Allows researcher to share pre-engagement check information across organisations
 - Relies on assurances of those who have done checks
 - Removes duplication and speeds up start-up
- Research in the NHS:
HR Good Practice Resource Pack



The Passport benefits researchers, NHS organisations and Universities because it:

- Promotes the **consistent** use of honorary research contracts by the NHS
- Provides clear **guidance** on their use
- Provides a streamlined **standard system** to apply for the contracts
- **Avoids repeat checks** for each contract
- Clarifies **responsibilities** of NHS hosts and Higher Education Institution employers



UK-wide information and resources:

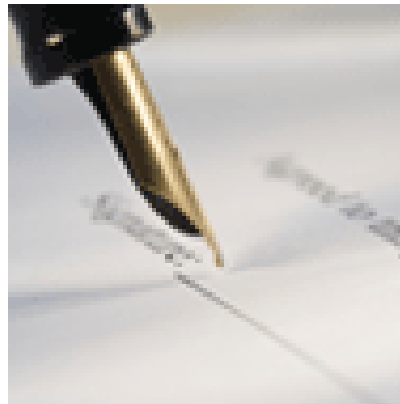
<http://www.ukcrc.org/researchpassport.aspx>

Resource Pack:

http://www.nihr.ac.uk/systems_research_passports.aspx

UKCRC Model Agreements

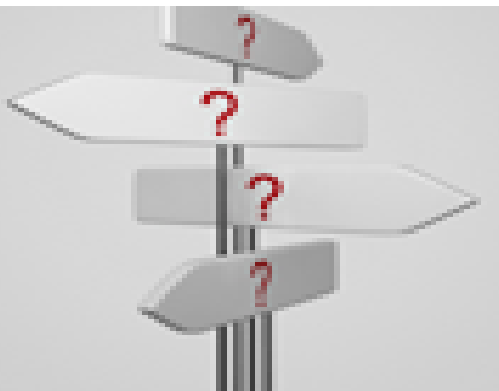
- Pharmaceutical clinical trials (mCTA)
- Clinical trials involving a CRO (tripartite mCTA)
- Clinical investigation of medical devices (mCIA)
- Non-commercial research in the health service (mNCA)



UKCRC R&G Advice Service

- Support for local advice providers
- Online resources – toolkits, Q&As
- Supported by network of regulators, governance bodies and policy makers

www.ukcrc-rgadvice.org



NIHR Research Support Services

- Improve the quality, speed and efficiency of NHS R&D processes
- The work recognises that R&D offices need additional support to maximise the benefits of this streamlining activity and to aid consistency
- It will provide resources such as standard operating procedures, risk management and training
- News will appear on the NIHR Portal

Any questions?