

HSC R&D APPLICATION GATEWAY

FREQUENTLY ASKED QUESTIONS (March 2015)

What is the role of the Gateway?

The Gateway facilitates and supports the process of gaining Research Governance Permissions for multicentre studies which are taking place in Northern Ireland (NI). It works in partnership with the HSC Trusts, to ensure that multi-centre research applications are managed efficiently.

These applications can be multicentre studies which are led from England, Scotland or Wales and they are able to use the Gateway to help manage their sites in Northern Ireland. Similarly studies which are led from Northern Ireland will use the Gateway for co-ordination of studies with sites in England, Scotland or Wales.

Does the Gateway give HSC Research Governance Permission for a research study?

No, this is still the role of the HSC Trust R&D Offices in Northern Ireland.

All HSC Trusts/NHS organisations must give HSC/NHS Research Governance Permission to host a research study. The principles of good research governance encourage HSC/NHS organisations to adapt their processes to reflect their specific role in a given research study.

What approvals are required?

The approvals required for a research study depends on the type and design of the study. All research carried out in the HSC/NHS will require HSC Research Governance Permission, and the majority of studies will also require a favourable opinion with a NHS Research Ethics Committee (REC).

Other approvals may be needed from regulatory bodies such as the Medicines and Healthcare products Regulatory Agency (MHRA), THE National Information Governance Board (NIGB), the Administration of Radioactive Substances Advisory Committee (ARSAC) and other regulatory bodies as required.

The R&D Office of your local HSC/NHS organisation will be able to provide advice on the approvals required for the study.

What is IRAS?

IRAS is the Integrated Research Application System (IRAS)

All applications for HSC Research Governance Permission (and to other regulatory and governance bodies) should be submitted for review using the application forms in IRAS. IRAS is a web based system that can be accessed at: www.myresearchproject.org.uk

The application forms and checklists for your research study are generated in IRAS.

New users should familiarise themselves with IRAS using the free e-learning tool. IRAS provides questions specific guidance that can be accessed by clicking the information buttons alongside a question or accessed from the Help menu.

IRAS Technical helpdesk

Telephone: 020 70430734

Email: helpdesk@myresearchproject.org.uk

What documents do I need to submit with my application?

You should submit all the applicable documents that are listed in the NHS R&D Form submission Checklist. Ideally documents should be submitted as PDF Files, or files created in standard computer software such as Microsoft Office. If there are a large number of documents you can submit them as a ZIP file or split them across a few submission emails.

What is the checklist and why do I need to complete one?

Each NHS R&D Form has its own submission Checklist. To find the checklist, select the NHS R&D Form in IRAS. You will then be able to see the Checklist tab. Clicking on the tab you will see the submission checklist you need to complete.

The checklist is used to confirm all expected documents have been received. It is important that the correct checklist is used because every study and application form is different.

How do I save my completed form as a PDF file?

Select the application form in IRAS and you will then be able to see the Submission tab. Click the "Proceed to submission" button to save a PDF file of your form. The form will then also be available at the end of the Submission tab page under "Submission History".

Do I need to wait for other approvals before making my submission?

No. The application for HSC Research Governance Permission is received in parallel to application for ethical review or other relevant regulatory approvals.

HSC Research Governance Permission will be subject to other necessary approvals being in place.

My study only involves HSC/NHS staff. Do I need to apply for HSC Research Governance Permission?

Yes. HSC Research Governance Permission is required for all research studies involving HSC Patients (including tissues, organs or data), HSC Staff or using HSC resources (facilities or equipment).

Is there a guidance document to help me apply?

Please access the guide for researchers/applicants, V4.0, Updated February 2015

My study has many research sites across the UK. How do I apply for HSC/NHS research permission in each UK Country?

Each nation of the UK has a co-ordinated permissions system. Northern Ireland has an agreement with the other UK nations to share the NHS R&D Form & Study Wide Document Set where they are identified as a participating nation in the NHS R&D Form.

Once the application package has been shared, each nation will make the application available to the participating sites which are situated within their own nation.

Further details can be found at:

England	Scotland	Wales
NIHR CSP Unit Tel: 01133432314 Website: www.crnc.nihr.ac.uk/csp Email: crnc.cspunit@nihr.ac.uk	NRS Permissions CC Tel: 01224552690 Website: www.nhsresearchscotland.org.uk/nrspcc Email: nhsg.nrspcc@nhs.net	NISCHR PCU Tel: 01874615959 Website: www.bit.ly/walesnischrpcu Email: NISCHR.PCU.Allwales@wales.nhs.uk

How do I contact the Gateway?

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