NHS Research Scotland
Permissions Coordinating Centre
(NRS Permissions CC)

Coordinating faster permissions for Scotland

A guide to who we are and what we do
Scotland has a justly deserved reputation for clinical research excellence. This is helped by its stable population with a positive attitude to clinical trials and unique patient identifiers linked to clinical records for all 5.3 million of our population. Supporting such high quality research is one of the main objectives of the NHS in Scotland. Achieving this requires an effective and responsive infrastructure to encourage researchers to bring studies to Scotland and to ensure that obtaining NHS R&D permission is a smooth and rapid process.

The NHS Research Scotland Permissions Coordinating Centre (NRS Permissions CC) acts as a central point of contact for all non-commercial investigators and industry wishing to carry out multicentre studies in Scotland. The Centre facilitates feasibility assessments across Scotland and manages and tracks the streamlined process for obtaining NHS R&D permission in all Scottish sites; only one set of project documents need be submitted. It can also assist organisations wishing to access Scotland’s world-leading clinical academic investigators, who have expertise across a wide range of health-related research fields, by putting them in touch with the right person.

Already through the work of NRS Permissions CC and R&D offices, significant improvements have been made in the time taken to gain permission to undertake multicentre research within NHS Scotland. Maintaining this performance and standard of service to researchers and industry will remain a key priority going forward.

John Savill, May 2010
NHS Research Scotland (NRS)

NRS is an initiative implemented by the Chief Scientist Office of the Scottish Government and Health Boards to streamline the NHS R&D management permission process for multicentre research in Scotland.

The NRS network consists of:

- **Fourteen Scottish Health Boards** (with eleven R&D offices), including four Boards with medical schools active in clinical research. Experienced staff within R&D offices carry out the technical reviews to enable permission to be given for research projects by the relevant NHS organisation.

- **NHS Research Scotland Permissions Coordinating Centre**
  NRS Permissions CC based in Aberdeen has a dedicated administrative team responsible in the main, for managing the NHS R&D management permission process across Scotland, for commercial and non-commercial multicentre research projects.

- **National Database**
  NRS Permissions CC team uploads project documents into a single web-based informatics system called the Scottish Research Database Application (SReDA), to help manage the permissions process and increase efficiency.

- **Members of the Chief Scientist Office (CSO)**
  Responsible for NHS research infrastructure and policy.

1 Multicentre = more than one Health Board in Scotland or one Scottish Health Board when part of a UK-wide study
NRS Permissions Coordinating Centre

What we do

• Act as a single point of contact for industry and investigators.
• Facilitate feasibility assessments across Scotland.
• Manage the streamlined process to obtain NHS R&D permission for multicentre research projects in Scotland.
• Handle commercial and non-commercial research projects (Phase I-IV).
• Link with equivalent centralised offices in England and Wales to coordinate the global governance checks for UK-wide studies.
• Collate the national document set for multicentre research project applications and upload into SReDA.
• Track projects and timelines for the permissions process.
• Maintain a register of clinical researchers in Scotland.
• Actively work to increase the number of commercial trials coming to Scotland.
• Act on customer feedback.

Benefits

• Access to helpful, friendly, informed staff by phone, email or in person, to help guide you through the NHS Scotland multicentre R&D permissions process and to answer any queries.
• A single point of entry for multicentre permission applications.
• Project documents need only be submitted once.
• Centralised project coordination and management.
• Improved efficiency due to NRS streamlined and best practice procedures.
• Improved efficiency and compliance through use of the web-based database for all projects - SReDA.
• Reduced time to gain permissions which fully satisfy all governance and regulatory requirements.
• We maintain oversight of NRS R&D permission performance.
• Project tracking: we can tell you where your project is in the system at any time.
NHS R&D Management Permission - when is it required?

NHS R&D management permission is required if a project is ‘research’ (rather than service evaluation or audit), and if it involves NHS patients (including tissues, organs, data), NHS staff, NHS resources (facilities, equipment). It is required at each site before research can begin.

To help you decide if your project requires R&D permission and other approvals, visit the National Research Ethics Service (NRES) website (www.nres.npsa.nhs.uk), and the IRAS website (https://www.myresearchproject.org.uk).

Before I apply
1. Establish whether the project is ‘research’.
2. Assess whether the research requires R&D permission.
3. Confirm participation of staff at all sites/Health Boards.
4. Determine if the project requires ethical review.
5. Assess if other approvals are required (eg. MHRA).
6. Contact NRS Permissions CC for a checklist of the required submission documents.

How Do I Apply?

Apply for NHS R&D management permission using the Integrated Research Application System (IRAS).
Application for R&D permission may be made at the same time as application for ethics approval.
1. Complete an IRAS R&D Form.
2. Send the IRAS R&D Form to NRS Permissions CC with supporting submission documentation.
3. Send completed Site-Specific Information (SSI) Forms to participating Principal Investigators (for authorisation prior to submission to local R&D offices).

Final R&D permission will be confirmed only after a favourable ethical opinion has been given.
NRS R&D Permission Process for Scottish Sites (Multicentre Research)

Applicant notifies NRS Permissions CC of new multicentre research project

NRS Permissions CC sends checklist of documents for submission to applicant

Applicant sends IRAS R&D Form with supporting documentation (electronically) to NRS Permissions CC; and SSI Forms to Principal Investigators

NRS Permissions CC checks / uploads document set into SReDA; notifies participating R&D offices of availability of documents for review

Generic Review

Local Reviews

Certificate of Compliance issued

Local management permission letter issued by R&D offices to Principal Investigators/Chief Investigator/
NRS Permissions CC

NRS Permissions CC will confirm when they have a full document set

Project Tracking and Management

NRS has project management systems in place to monitor and successfully progress projects through the permissions process. Key dates are recorded to allow visibility of project status. Key initiatives that are in place to help achieve efficient multicentre R&D permission include:-

- Two-weekly NRS teleconference with key R&D office staff
- Circulation of a regular ‘Project Alert Report’ to R&D offices highlighting projects that have passed a given permission timeline; NRS staff prioritise action for these projects to achieve subsequent prompt local management permission(s).
- Escalation procedure, to resolve project issues that require action by NHS senior management.
Performance: R&D Permission Times

R&D permission time is measured from receipt of a full document set to issue of local management permission at each participating Health Board R&D office.

How are we doing?
In the first 11 months since NRS Permissions CC began to accept commercial studies, a median R&D permission time of 19 working days has been achieved. Over the last quarter of this period, median permission time stood at 16 working days. For non-commercial studies, there has been an equally positive trend in reduced times for gaining R&D permission with medians as follows:
• July-December 2008: 41 working days
• January-June 2009: 24 working days
That’s a reduction in median permission time of 41%
• July-December 2009: 24 working days
• January-March 2010: 21 working days
NRS is constantly striving to improve it’s performance.

NRS Metrics

![Commercial studies: R&D permission times (May 09-Mar 10)](chartCommercialStudies)

Median: 19 working days

![Non-commercial studies: R&D permission times (May 09-Mar 10)](chartNonCommercialStudies)

 Median

R&D permission time (working days)

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<th>Jan-Jun 09</th>
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Site permissions (n = 58)
How Can I Help Speed Up the Process?

There are a number of ways that research applicants can help gain quicker NHS R&D permission for their studies in Scotland:-

• Apply for NHS R&D permission at the same time as ethics approval.

• Send correct versions of all necessary documents to NRS Permissions CC electronically.

• Employ Scottish model contracts “as published”.

• Obtain Principal Investigators’ support prior to sending out Site-Specific Information (SSI) Forms and let them know that the SSI is on its way.

• Submit any amendments sent to an ethics committee, to NRS Permissions CC as well.

Commercial customers should also:-

• Employ the UK CRN Costing Template as a basis for costing the study for Scotland.

• Get in touch with NRS Permissions CC early to discuss the need for Confidentiality Agreements - if applicable.

• Get in touch early on in the process with the Commercial Manager of the lead R&D office, to initiate study contract and finance discussions.

NRS Permissions CC Service Offerings

In addition to managing the NHS R&D permissions process for multicentre research in Scotland, an important part of our work is to:-

• Coordinate feasibility assessments.

  • NRS Permissions CC will provide a Scotland-wide response of Scottish Investigator interest and patient recruitment capability within 2 weeks.

• Coordinate global governance checks for UK-wide studies.

  • If the Chief Investigator leading a UK-wide study is based in Scotland, NRS Permissions CC will receive the project application and coordinate the global governance checks on behalf of the UK. As soon as the NRS Certificate of Compliance is available, NRS Permissions CC will forward it to the equivalent UK centralised office(s), either the National Institute of Health Research Coordinated System for gaining NHS Permission Unit (NIHR CSP Unit), or the All Wales Primary Care Research Management & Governance Office (RMG office).

  • If the Chief Investigator is based in England or Wales, either the NIHR CSP Unit or the RMG office will receive the project application initially. They will send email notification along with the IRAS R&D Form to NRS Permissions CC, so that we may promptly contact the researcher to progress R&D permissions within Scotland without delay.

Please contact NRS Permissions CC if you would like to know more about the above processes.
Access to Investigators and Patients

NRS Permissions CC holds a **register of clinicians** who conduct clinical research in Scotland.

The Permissions CC team can also assist companies with access to Scottish Investigators and patients by direct links with the **Scottish Disease Research Networks**:-

- Cancer ([www.scrn.org.uk](http://www.scrn.org.uk))
- Dementia ([www.sdcrn.org.uk](http://www.sdcrn.org.uk))
- Diabetes ([www.sdrcn.org.uk](http://www.sdrcn.org.uk))
- Medicines for Children ([www.scotmcn.org](http://www.scotmcn.org))
- Mental Health ([www.smhrn.org.uk](http://www.smhrn.org.uk))
- Primary Care ([www.sspc.ac.uk](http://www.sspc.ac.uk))
- Stroke ([www.scotland.uksrn.ac.uk](http://www.scotland.uksrn.ac.uk))

We also have access to UK Clinical Research Network National Institute for Health Research Speciality Groups through **twenty-six Scottish Leads**, maximising potential interest from Scottish Investigators for feasibility for disease-specific trials.
Collaborations

Scotland has world class clinical research infrastructure situated across its major population centres. As well as state of the art biomedical imaging, genomics, proteomics and health informatics platforms, this infrastructure is complemented with leading clinical academic expertise which spans the diverse range of disease and therapeutic areas confronting 21st century healthcare today.

The Scottish Academic Health Sciences Collaboration (SAHSC) provides a good example of just one of a number of collaborative initiatives taking place in Scotland that is capitalising upon, as well as further developing, existing clinical research infrastructure.

The SAHSC is a recently created partnership involving four of Scotland’s largest Health Boards and their partner university medical schools in Aberdeen, Dundee, Edinburgh and Glasgow. Supported by a £10M investment it offers a strong platform for patient-oriented research collaborations involving all of the partner Health Boards and universities.

**NRS Permissions CC has an important role to help put you in touch with key clinical academic researchers:-**

- To help answer key questions around trial feasibility across different sites.
- To develop mutually beneficial research partnerships and collaborations with the NHS and academic institutions in Scotland.

NRS Permissions CC Interactions

**ABPI:** Association of the British Pharmaceutical Industry  
**CSP:** Coordinated System for gaining NHS Permission  
**RMG:** Research Management & Governance  
**SAHSC:** Scottish Academic Health Sciences Collaboration  

**NRS Permissions CC** interacts with:

- **ABPI**  
- **RMG OFFICE**  
- **NRS STRATEGY GROUP**  
- **INVESTIGATORS**  
- **NATIONAL DATABASES COORDINATOR**  
- **SAHSC**  
- **CSP UNIT**  
- **CHIEF SCIENTIST OFFICE**  
- **SCOTTISH DISEASE RESEARCH NETWORKS**  
- **R&D OFFICES**  
- **COMMERCIAL COMPANIES**  
- **SCOTTISH ENTERPRISE**
Why Do Research In Scotland?

**Patients**
- Ideal patient population.
- 5.3 million patient records linked to unique patient identifiers.
- High recruitment potential / high number of patient beds.
- Patient Disease Registers.

**Science**
- Clinical and academic excellence - world class research.
- Internationally-renowned pioneering medical research.
- Landmark clinical trials eg. West of Scotland Coronary Prevention Study (WOSCOPS).

**Networks / Support**
- State of the art equipment, research facilities, technologies.
- Scottish Disease Research Networks.
- Government investment to create a world class clinical research infrastructure.
- Scotland has a highly collaborative research environment.
NRS Permissions CC is funded by the Chief Scientist Office and Scottish Enterprise.
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