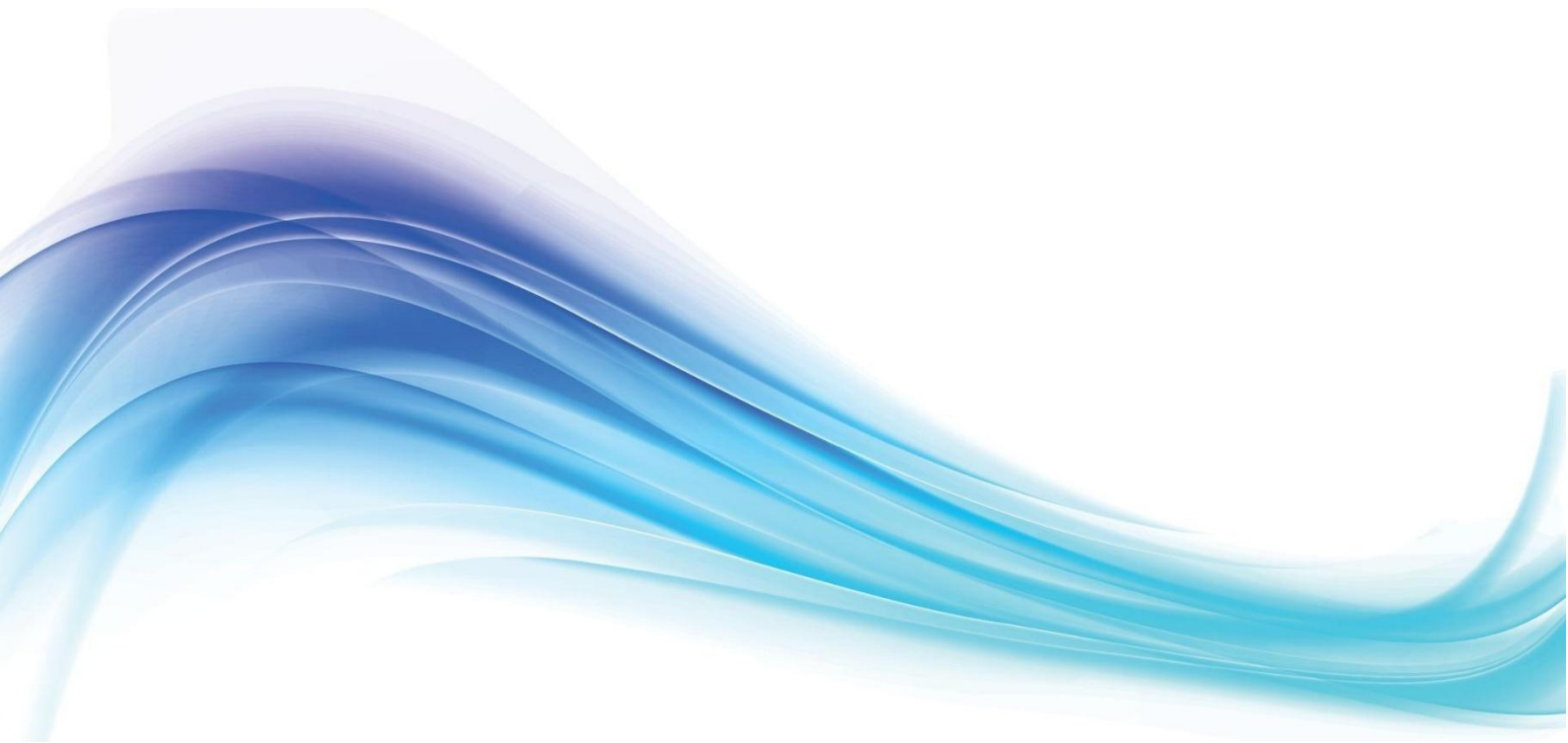




# A Handbook for Researchers involved in NHSGGC Sponsored Non-CTIMP studies

Version 1, 14.07.2026

Non-CTIMPS are studies which **do not** use Investigational Medicinal Products (IMPs) or Clinical Investigation of a Medical Device (CIMD) as defined by the Medicines and Healthcare products Regulatory Agency (MHRA)



## List of Contents

|                                                                       |             |
|-----------------------------------------------------------------------|-------------|
| <b>Research Governance: The Basics .....</b>                          | <b>3</b>    |
| <b>Is it Research?.....</b>                                           | <b>4</b>    |
| <b>Conducting your Research.....</b>                                  | <b>5</b>    |
| <b>Sponsorship, Peer Review &amp; Insurance .....</b>                 | <b>6</b>    |
| <b>Preparing and costing a proposal .....</b>                         | <b>10</b>   |
| <b>Schedule of Events Cost Attribution Tool (SoECAT) .....</b>        | <b>11</b>   |
| <b>Document Design.....</b>                                           | <b>13</b>   |
| <b>How do I apply? (IRAS Application submission).....</b>             | <b>15</b>   |
| <b>R&amp;I Local Approval .....</b>                                   | <b>17</b>   |
| <b>When to contact R&amp;I .....</b>                                  | <b>19</b>   |
| <b>Research only Involving NHS Staff as participants.....</b>         | <b>20</b>   |
| <b>Other Approvals.....</b>                                           | <b>21</b>   |
| <b>ICH GCP .....</b>                                                  | <b>23</b>   |
| <b>Research Passport .....</b>                                        | <b>24</b>   |
| <b>Modifications.....</b>                                             | <b>26</b>   |
| <b>Participating location set up.....</b>                             | <b>28</b>   |
| <b>Safety Reporting .....</b>                                         | <b>3030</b> |
| <b>Audit .....</b>                                                    | <b>3231</b> |
| <b>End of study .....</b>                                             | <b>332</b>  |
| <b>NHSGGC R&amp;I Tips .....</b>                                      | <b>354</b>  |
| <b>Useful Links and Resources: .....</b>                              | <b>365</b>  |
| <b>Appendix A – Defining Research .....</b>                           | <b>376</b>  |
| <b>Glossary - Commonly Used Research Abbreviations and Terms.....</b> | <b>387</b>  |

## Research Governance: The Basics

Research Governance may loosely be defined as a range of regulations, principles and standards which exist to achieve and improve research quality across all aspects of health and social care.

Research Governance aims to:

- Safeguard research participants
- Protect researchers
- Enhance ethical and scientific quality
- Minimize risk
- Monitor performance
- Promote good practice

Of these aims, the touchstone of research governance is safeguarding the dignity, rights, safety and wellbeing of all research participants.

### The Research Governance Framework (RGF)

The Research Governance Framework for Health and Social Care (RGF) is a Department of Health document which sets out the broad principles of good research governance. It ensures that health and social care research in the UK is conducted to the highest standards.

The RGF acts as a key text, underpinning the conduct of research in the NHS; it is implemented and enforced by NHS Greater Glasgow & Clyde's Research & Innovation Department (R&I Department).

The aim of the RGF is not to provide a single document that addresses all legislation, standards and good practice guidelines – but to promote a quality research culture where excellence is promoted and where there is visible and strong research leadership and expert management.

The UK government is actively transforming the clinical research system through the UK Clinical Research Delivery (UKCRD) program, which aims to:

- Improve access to research.
- Tackle major health issues.
- Reduce inequalities.
- Create a world-leading research environment

# Is it Research?

## How do I know if my project is 'research'?

Early in the study planning process, you need to first assess if the project being developed is research, service evaluation or audit. Not all projects undertaken within the NHS are 'research.' The term 'research' has a specific meaning in the RGF and if a proposal does not fall within this definition it will not require review by a REC or approval by an NHS Research & Innovation (R&I) office.

Activities which do not fall within the definition of 'research' include:

- Audit
- Service Evaluation
- Patient & Staff Surveys
- Case Studies or Case Reports
- Consensus Methods

Applications for REC review may also be made on a voluntary basis for research tissue banks/bio banks and research databases.

The Health Research Authority (HRA) [decision tool](#) can help you decide if your study is research.

Please see below a summary about these project categories. You can find a more exhaustive description in appendix A – Defining Research Table. If you're unsure please contact the R&I department.

## Conducting your Research

To conduct your study you must:

- [Identify a sponsor](#)
- Be adequately funded
- Have a favourable ethical opinion from a research ethics committee
- Have NHS Management Approval (R&I approval) to conduct the study. Management approval is the Scottish equivalent of England & Wales's Capability & Capacity.
- Maintain a Trial Master File – [form56-001h v1-0.docx](#)
- Receive informed consent from the participant
- Collect accurate data.
- Create a clear audit trail/ monitoring plan if R&I deemed applicable.
- Be aware of the safety reporting requirements
- Conduct the study to Good Clinical practice guidelines

### **When can my Research begin?**

Once all the necessary approvals required for any research have been received and R&I Local management approval has been granted, the research can proceed, otherwise insurance is not valid for your trial. Please note it is a condition of any Research Ethics favourable opinion that 'R&I Management Approval' is given for each NHS organisation participating in the research before commencing.

# Sponsorship, Peer Review & Insurance

## What is a sponsor?

A sponsor is an organisation (or group of organisations) that accepts responsibility for ensuring that there are proper arrangements to initiate, manage, monitor and finance a project. The RGF requires that all research taking place in an NHS or social care context must have a sponsor.

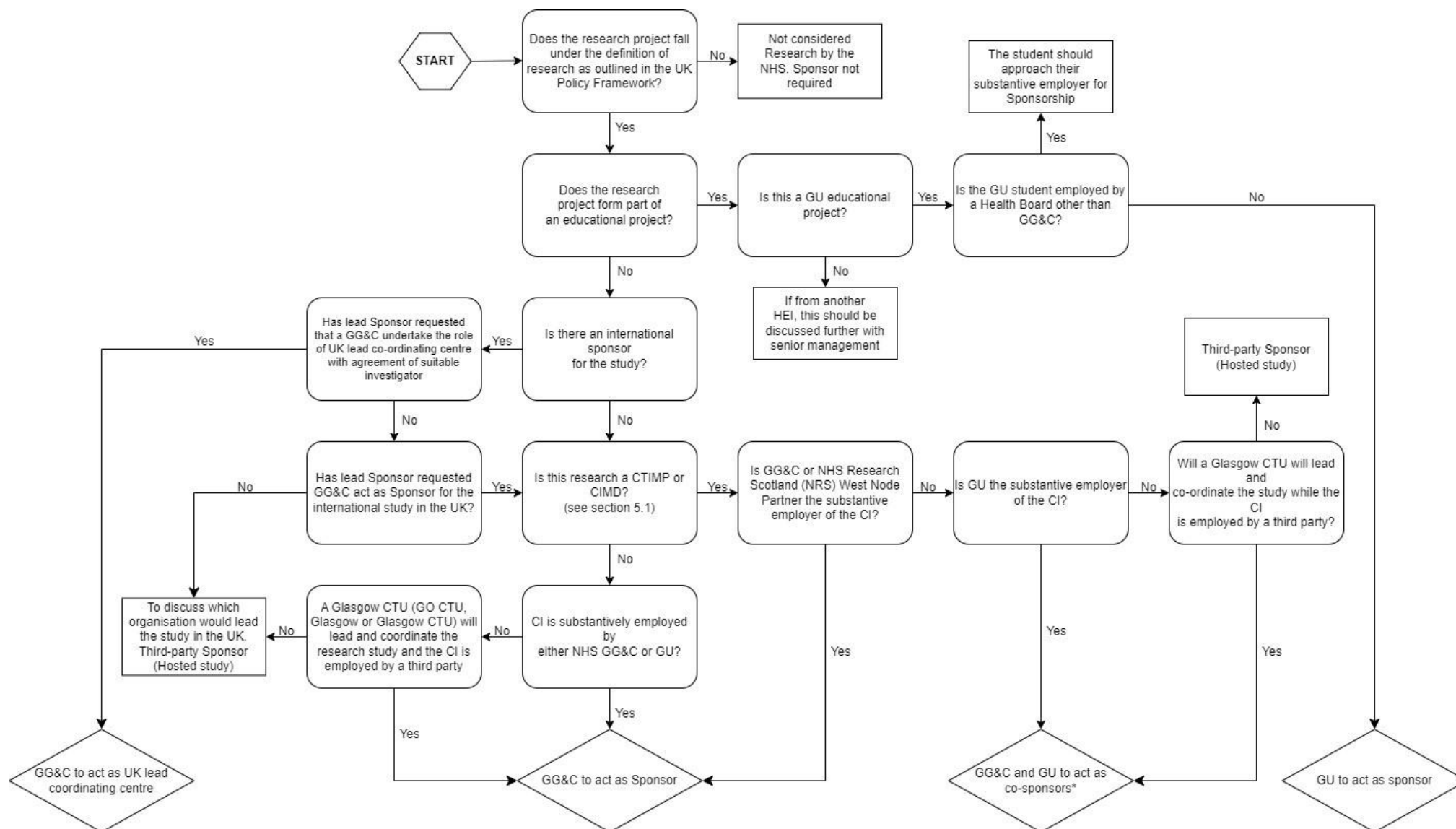
## Who may act as sponsor?

Any organisation that is a legal entity and which funds, initiates, hosts or employs staff involved in research may act as sponsor.

## Will NHSGGC sponsor my research?

NHS Greater Glasgow & Clyde health board is registered with the Department of Health as willing and able to act as a sponsor under the RGF. This does not mean that NHSGGC will accept sponsorship for all research requiring a sponsor.

NHSGGC will consider accepting sponsorship using the following flowchart:



To request NHSGGC to act as the sponsor for your study, please email the following documents to [ggc.randigrantapplications@nhs.scot](mailto:ggc.randigrantapplications@nhs.scot):

- Completed **Strategic Form** ([form51-010e v2-0.docx](#) – **Form 51.10E**)
- **NHSGGC Costing Form** ([form51-010a v6-0.xlsx](#))
- Any other relevant supporting information e.g. draft proposal or protocol.

Once your application has been received by R&I, a reference number will be assigned. Please ensure this reference is included in all future email communications (in the subject line).

Following submission, a meeting will be arranged with an R&I Coordinator or Facilitator to review the Strategic Form together.

### **What are the sponsor's responsibilities?**

The sponsor's primary responsibility is to safeguard the rights, safety, dignity and well-being of research participants. This responsibility prevails over the interests of science.

In doing so, the sponsor will accept responsibility for securing the necessary arrangements to conduct the research and will ensure that all the necessary authorisations have been obtained before commencing.

### **Can the sponsor delegate its responsibilities?**

No, the sponsor can delegate any and all of their functions but cannot delegate responsibility, which always remains with them. These responsibilities can further be delegated among members of the research team provided this is recorded in a 'delegation of duties log.'

### **Peer Review**

Peer review is a system where a research proposal or protocol is scrutinised by independent experts to promote quality research and prevent poorly designed research from taking place when the study is funded by a [non-eligible funder](#). Depending on the type of research, this can also be carried out by the academic supervisor or within the research team. R&I may require confirmation of peer review by requesting 2 independent reviewers. R&I will then send the study protocol and a copy of the [peer review form](#) to be completed. Peer review will include endowments.

*NHSGGCs SOP on Peer Review – (51.003) [sop51-003 v5-0.pdf](#)*

*NHSGGCs SOP on Sponsorship – (51.007) [sop51-007 v6-0.pdf](#)*



# Insurance & Indemnity

## CNORIS

A key responsibility of the sponsor is to put in place arrangements for compensating participants if they suffer any harm as a result of their involvement in a project.

For research sponsored by NHSGGC, the NHS Indemnity Scheme applies and provides unlimited cover for NHS staff, medical academic staff with honorary contracts and those conducting research for negligent harm. Non-negligent harm (i.e. harm that has been caused through no fault of those conducting research) is not covered by this scheme, however ex gratia payments may be considered by the Trust in limited circumstances.

More information on CNORIS can be found using the following link: [Guide to the Clinical Negligence and Other Risks Indemnity Scheme \(CNORIS\) | National Services Scotland](#)

## Other insurance

All NHSGGC contracts are covered under CNORIS. However, if the Chief Investigator (CI) is employed by the University of Glasgow (GU), as their substantive employer, then the design of the protocol will be covered by GU's insurance. To make sure you are fully covered you can contact GU's research governance & regulation team [University of Glasgow - Research - Strategy and policies - Our policies & guidance - Further Information](#)

Please note: This guidance is not exhaustive and may not cover all insurance scenarios. Additional coverage may be necessary depending on the nature of the study.

## Preparing and costing a proposal

A high quality proposal will maximise the chance of success, before submitting a costing request form and strategic plan to GGC you should consider the following:

- **Funder guidelines** - Each funder will have specific criteria for their funding schemes including eligibility to apply. Ensure you are familiar with the application requirements of each specific scheme. Failure to meet these requirements may lead to rejection at the first stage of funder review.
- **Assessment criteria** - Check the funder's assessment criteria carefully to ensure these can be met before investing significant time in developing the proposal. Funding decisions will be based on assessment against the criteria.
- **Timescale** - Sufficient time should be allowed to develop a research proposal and re-work it if required. Also allow at least **20 working days** (10 days for R&I to review and get additional costs if applicable & 10 days for finance to review and provide the costs) for R&I to provide the necessary internal approvals and costs before final submission to the funder.
- **Data Protection Impact Assessment (DPIA) and/or System Security Policy (SSP)** Before submitting a grant application, you must assess whether a DPIA and/or SSP is required and this must be included in NHS costings.
  - **DPIA** - A DPIA is required where your study involves personal data and presents a risk to participants, which is common for research using health data. A Rapid DPIA may be appropriate for small, low risk projects with no third parties and data remaining within NHSGGC.
  - **SSP** - An SSP is required where your study uses any data system, platform or software, including databases, apps or cloud solutions. Researcher must first complete a [Risk Register](#) and the Cyber Security team will determine what should be put in place.

please email the following documents to [ggc.randigrantapplications@nhs.scot](mailto:ggc.randigrantapplications@nhs.scot):

- Completed **Strategic Form** ([form51-010e v2-0.docx](#))
- **NHSGGC Costing Form** ([form51-010a v6-0.xlsx](#))
- Any other relevant supporting information

Once your application has been received by R&I, a reference number will be assigned. Please ensure this reference is included in all future email communications.

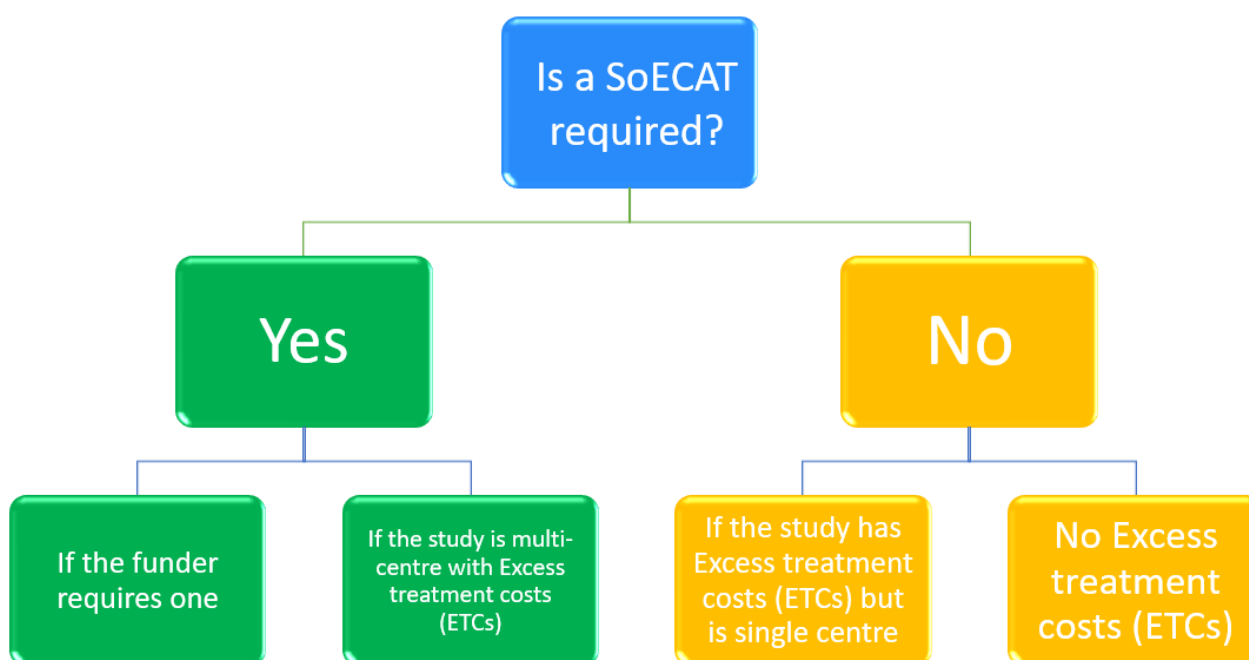
Following submission, a meeting will be arranged with an R&I Coordinator or Facilitator to review the Strategic Form together.

# Schedule of Events Cost Attribution Tool (SoECAT)

SoECAT is a cost attribution template designed to support correct cost attribution at application for research cost funding, to ensure that full location-level research costs are recovered. It provides the Excess Treatment Cost (ETC) per participant value. More information can be found at [Online SoECAT Guidance | NIHR](#)

## When do I need a SoECAT?

A SoECAT might be required at the funding stage. Always check the specific guidance for your funding call for more information. Some examples of when a SoECAT is required is the following:



This list is not extensive. To find out more information about if a SoECAT is required you can contact the finance team [R&D.Finance@nhs.scot](mailto:R&D.Finance@nhs.scot).

## How do I apply?

1. Create an Account in CPMS
  - Go to the NIHR Central Portfolio Management System (CPMS).
  - If you don't have an account, click "Create Account" and follow the instructions.
  - If you already have an NIHR or IRAS login, you can use that to sign in.
2. Start a New Service Application
  - Once logged in, click "Apply for a service for a new study" on the CPMS homepage.
  - Select "Non-commercial" as your study type.
  - Choose "Schedule of Events Cost Attribution Tool (SoECAT)" from the available services

3. Complete the SoECAT Form
  - Fill in all required fields, including study title and IRAS ID.
  - Use the online guidance tool embedded in the SoECAT form for help at each stage.
  - You can also access the Online SoECAT Guidance Module via NIHR Learn (requires an account)
4. Add a Study Representative (R&I Coordinator/Facilitator)
  - Ensure a lead location-based Study Representative is added to review participating location resources.
  - You can manage study contacts via the “My Service Applications” dashboard in CPMS
5. Request Authorisation
  - Select GGC and It will be automatically sent to the local AcoRD Specialist.
  - Allow at least 10 working days for authorisation.
  - Once authorised, include the funder export Excel document in your grant application
6. Submit the SoECAT
  - After receiving a grant award, go to “My Service Applications” in CPMS.
  - Complete the Submission tab, upload the award letter, and submit the SoECAT.
  - Download a funder copy (Click actions then funder export) and send to your R&I coordinator/facilitator.

**For help and information can be found using the following link: [Online SoECAT Guidance | NIHR](#)**

*NHSGCCs SOP on Preparation and Review of Grant Applications and Costs – (51.010) [sop51-010 v5-0.pdf](#)*

# Document Design

Once a funding application has been successful, you need to submit your full document pack to your R&I coordinator/facilitator to review. The documents you need would have been highlighted when the strategic form was completed.

## What documents to include

For a full list of documents a templates are available on the [IRAS website](#). [Prepare study documentation - Health Research Authority](#)

### 1. Research Protocol

Should clearly outline:

- Study objectives
- Methodology
- Participant criteria
- Data collection and analysis plans

You can use the protocol template found at HRAs Website: [Protocol - Health Research Authority](#)

### 2. Participant Information Sheet (PIS), Consent Form & Any patient facing documents

Must be clear, concise, and ethically sound. You can use the PIS guidance form. [guideline51-002 v1-0.pdf](#). Your PIS and consent forms Should include:

- Purpose of the study
- What participation involves
- Risks and benefits
- Data protection and confidentiality
- Contact details for queries or complaints.
- GDPR transparent wording [Transparency wording for all sponsors - Health Research Authority](#)
- Make sure [ggc.complaints@nhs.scot](mailto:ggc.complaints@nhs.scot) email is included.

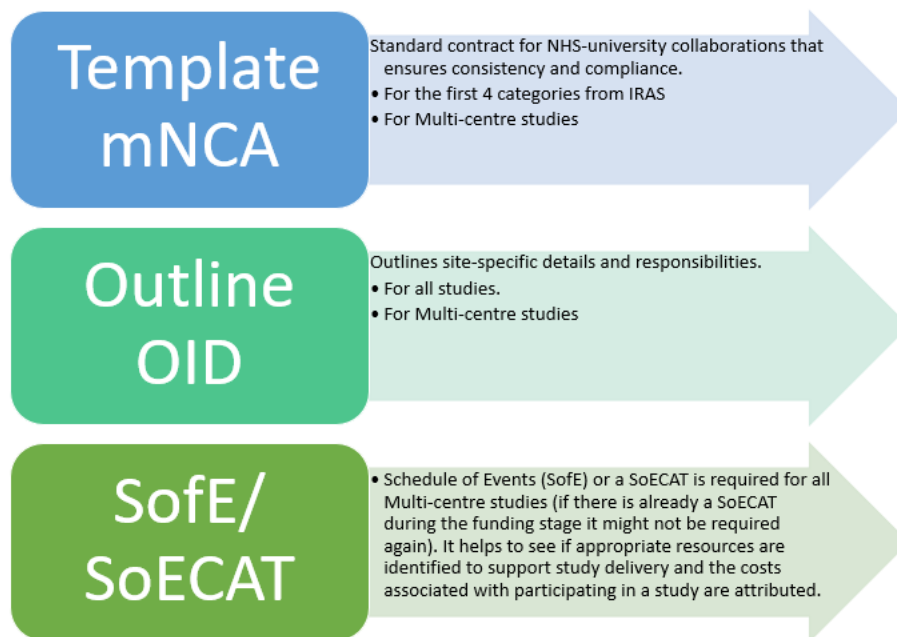
More information can be found at [Informing participants and seeking consent - Health Research Authority](#).

### 3. IRAS Form

IRAS Forms can either be transferred electronically through IRAS to the R&I Coordinator/facilitator using their IRAS ID (email address) or the Researcher can save a pdf of the draft form and email that to the R&I Coordinator. In order to set up an account you can follow the instructions under the IRAS application section.

#### 4. Participating location contracts and other documentation (Local Information Pack)

The mNCA (UK Model Non-Commercial Agreement), Organisation Information Document (OID), and Schedule of Events (SoE)/SoECAT may also be required for review by the R&I Coordinator or Facilitator. Please refer to the flow chart below for guidance on when these documents are necessary



[Organisation Information Document NonComm 28 April 2026 v2 0.docx](#)

NHSGCCs SOP on Protocol Development (51.001) - [sop51-001 v7-0.pdf](#)  
NHSGCCs SOP on PIS & ICF Development (51.002) - [sop51-002 v6-0.pdf](#)

# Research Ethics Committee Approval

## What is Research Ethics Committee (REC) Approval?

The Declaration of Helsinki (World Medical Association, as amended 2008), sets out the ethical principles for medical research involving human subjects – including research on identifiable human material and data. It is perhaps the most important document in the history of research ethics.

The role of Research Ethics Committees (RECs) is to safeguard the rights, safety, dignity and well-being of research participants by ensuring that research proposals have been designed and will be conducted in accordance with the Declaration of Helsinki. If they are satisfied that this is the case, they will offer a 'favourable opinion' for the research (often referred to as 'REC approval').

## When do I need it?

As a general rule of thumb, all research taking place within the NHS requires REC approval.

REC review is not normally required for research involving NHS or social care staff recruited as research participants by virtue of their professional role. However, NHS Research & Innovation (R&I) approval is still required. A single REC approval is typically sufficient for each study. However, if your study involves adults lacking capacity, additional REC approvals may be necessary. Please consult with an R&I Coordinator to confirm the requirements in such cases.

If you are still unsure you can use the HRA decision tool: [Do I need NHS Ethics approval?](#)

## How do I apply? (IRAS Application Submission)

Applications for REC approval and for other approvals necessary for a project can be made online via the [Integrated Research Application System](#) (IRAS). This system streamlines the process for seeking relevant approvals (e.g HRA) by ensuring that, as far as possible, details only need to be entered once for a single project and much of the form then self populated. To apply for REC the following steps apply:

- Prepare your study documents & send to R&I for review.
- Book your application in through the [Online Booking Service](#).

Guidance on how to use the online booking service [Online Booking Service - Health Research Authority](#)

- E-submit your applications in [IRAS](#)

Help on using IRAS use the following link: [Home - Getting the best from IRAS](#). Alternatively, contact the IRAS helpdesk [helpdesk@myresearchproject.org.uk](mailto:helpdesk@myresearchproject.org.uk) or phone 0207 0430744 (Monday to Friday 9 am to 5 pm).

Notify R&I once the IRAS application form has been submitted for authorisation. This authorisation confirms that the study has been reviewed and approved for submission on behalf of the Sponsor.

At the meeting of the REC, between 7 and 18 members will be present and will ask questions surrounding any ethical issues arising from your application. You should be prepared to clarify any ethical issues that may be raised.

## How long does it take?

A REC is required to give an ethical opinion on an application within **60 calendar days** from receipt of a valid application. Where further information is required to give an opinion, the REC may make a request in writing for further information. The clock will be suspended pending receipt of this information.

[Research Ethics Committee review - Health Research Authority](#)

*NHSGGC SOP on IRAS Preparation & Submission (51.014) - [sop51-014 v5-0.pdf](#)*



# NHS Research & Innovation (R&I) Approval

## What is R&I Approval?

'R&I Approval' relates to the process of reviewing and checking applications for research to take place within an NHS organisation, prior to giving written permission for the study to take place. It is also frequently referred to as **R&I Management Approval or Capability & Capacity**. In most NHS organisations, R&I is responsible for carrying out these checks before permission is given by the R&I officer.

## When do I need it?

Approval will be required from the R&I departments for each NHS organisation involved in the research, if the research proposal is to involve any one or more of the following:

- Patients and service users of the NHS;
- Individuals identified as potential participants because they are relatives or carers of NHS patients and services users;
- Patient data, organs and other bodily materials of past or present NHS patients;
- Foetal material and IVF involving NHS patients (under Human Fertilisation and Embryology Act 1990 and oversight by the Human Fertilisation and Embryology Authority (HFEA));
- Use of or potential access to NHS premises or facilities; and/or
- NHS Staff (whether as participants or research personnel);
- Study is funded by an eligible funder.

As a general rule, **R&I approval will always be required if REC approval is required** (see above). There may also be occasions where R&I approval is required when REC approval is not required (e.g. laboratory research on NHS premises) but contact your R&I coordinator/facilitator for confirmation.

## What does the process involve?

The RGF requires NHS organisations to ensure that before any research involving human participants, their organs, tissue or data commences:

- there are adequate arrangements and resources (finance, staff and facilities capacity) to meet the standards set out in the RGF through to project completion;
- an identified sponsor has taken on responsibility for the project;
- the project has received ethical approval (where required);
- other regulatory approvals are in place depending on the nature of the research;
- honorary contract /letter of access if NHSGGC is not your substantive employer
- Confirmation from the Head of Department, OID appendix and OID (where required)
- appropriate contractual arrangements are in place;

| R&I Local Approval                                                                                                             |
|--------------------------------------------------------------------------------------------------------------------------------|
| CI CV/GCP                                                                                                                      |
| Approvals e.g. Caldicott Guardian /PBPP/DPIA/LPAC/SafeHaven                                                                    |
| Localised LIP:<br>Localised OID<br>OID appendix email<br>HofD approval                                                         |
| Submitted Local Information Pack to NRS PCC (N/A for databases/tissue banks/single centre)                                     |
| Support department approvals (E.g. CRF, respiratory lab/ophthalmology/radiology if needed)                                     |
| CTEC Approval Date (Beatson studies)                                                                                           |
| Finance Review Completed                                                                                                       |
| Pharmacy approval (if applicable)                                                                                              |
| Project eligible for registration on public database (e.g. clinicaltrials.gov) (Top 4 categories on IRAS only)                 |
| Imaging support Form 58.004B completed                                                                                         |
| Contracts e.g (fully signed date) mNCA/mCTA/OID as agreement                                                                   |
| Local ARSAC compliant (if applicable)                                                                                          |
| Research Passports/HRCs/LOAs<br>Date valid documents and pre-engagement checks received:<br>Date documents were signed/issued: |

## How long does it take?

The length of time taken to obtain R&I approval varies depending on each individual project, the other approvals necessary, and the R&I offices at different NHS organisations.

We recommend that your application to the NHSGGC R&I is submitted as soon if all documents are submitted as a package. If you provide us with all the documents required as early as possible and are available to answer any further queries we may have, then this will help reduce the approval time.

## When to contact R&I after Local Approval

It is important that you make contact with R&I in the following circumstances:

- For any modifications (Substantial/MOID and/or Minor modifications)
- Where there are concerns regarding research misconduct, a breach of GCP, or a breach of confidentiality or data protection laws
- If you are having difficulties with patient recruitment
- Submitting participant accruals information
- When a project has closed to recruitment
- Providing end of study forms/final reports to REC.

**Please also contact R&I if you have any queries or concerns or there is any information about your research that you think we would like to know. R&I is here to help and support you with the research you are undertaking.**

*NHSGCCs SOP on R&I Local Management Approval (51.001) - [sop52-001\\_v-4-0.pdf](#)*

## Research only Involving NHS Staff as participants

### Do I need REC approval for a staff study?

REC review is not normally required for research involving NHS or social care staff recruited as research participants by virtue of their professional role.

However, the Research Ethics Service may accept an application for review of research involving staff if the proposal raises material ethical issues. This can be requested by the sponsor, chief investigator or host organisation.

It is important to remember that ethics approval is required if the research involves any other activity that falls within the requirements for ethical review. Information regarding activity requiring ethical review is available on the [HRA Website](#).

### Do I need R&I Approval for a staff study?

Yes. The Research Governance Framework for Health and Social Care still applies, and the research will continue to require R&I approval from each location involved.

The process for obtaining R&I approval for research involving NHS staff remains the same as for any other research project. Further information about the process for obtaining R&I approval is available on Page 13, above.

### Do I need to complete an R&I application form in IRAS for a staff study?

As R&I approval is still required for research involving NHS staff, you still need to complete an application for R&I approval via the Integrated Research Application System (IRAS) which can be found at: [www.myresearchproject.org.uk](http://www.myresearchproject.org.uk)

Within IRAS, it is possible to indicate in the Filter that a research project requires review by NHS R&I only. This will generate the necessary R&I application forms.

*NHSGCCs SOP on NHS Staff as Participants (52.017) - [sop52-017\\_v1-0.pdf](#)*

## Other Approvals

### **Confidentiality Advisory Group (CAG) for England & Wales**

NIGB approval is required for using patient information without consent. Approval will only be given where consent is impracticable and where pseudonymous or anonymous data will not suffice.

### **Public Benefit and Privacy Panels (PBPP) for Scotland (Multicenter)**

[PBPP](#) Reviews applications for access to NHS Scotland health data, including personal or sensitive information.

### **Caldicott approval (Single center studies)**

[Caldicott](#) approval refers to a review process within the NHS that ensures the responsible and lawful use of patient-identifiable information in research and other activities. It is overseen by a Caldicott Guardian, a senior person in each NHS organisation responsible for protecting the confidentiality of patient data and ensuring it is used appropriately, in line with the Caldicott Principles.

### **Administration of Radioactive Substances Advisory Committee (ARSAC) Certificate**

An ARSAC certificate is required for any clinician (at each research location) who wishes to administer radioactive materials to human subjects, for example nuclear medicine scans (including PET scans) and nuclear medicine therapies. This does not apply to routine X-rays or CT scans.

### **Human Tissue (Scotland) Act 2006 (HTA 2006)**

The Human Tissue (Scotland) Act 2006 (HTA 2006) primarily regulates the removal, storage and use of tissue and organs from deceased persons in Scotland. It is based on authorisation and applies to activities such as post-mortem examination, transplantation, education and research involving tissue from the deceased. The HTA 2006 does not regulate the use of tissue from living persons for research purposes. Researchers planning studies involving human tissue should ensure appropriate consent is obtained and comply with applicable ethical, governance and accreditation requirements.

The use of human tissue in research within NHS Scotland is also supported through the NHS Research Scotland (NRS) Research Tissue Bank and Research Tissue Resource accreditation framework, which promotes quality standards and governance for research involving human tissue.

### **Health Research Authority (HRA)**

**HRA** is a national body that oversees the ethical and regulatory review of health and social care research in **England**, working jointly with **Health and Care Research Wales (HCRW)** for studies in **Wales**. Scottish participating locations do not use the HRA/HCRW approval system.

# ICH GCP

## What is ICH GCP?

**Good Clinical Practice (GCP) is the internationally recognised ethical and scientific standard for designing, conducting, recording and reporting clinical research involving human participants.**

The GCP guideline is developed by the International Council for Harmonisation (ICH) and provides a harmonised framework to ensure that research is conducted to a high standard across different countries.

While GCP has traditionally been associated with clinical trials of investigational medicinal products (CTIMPs), the updated ICH E6(R3) guidance emphasises that its principles are applicable across a wide range of clinical research settings.

### **GCP ensures that:**

- The rights, safety and wellbeing of participants are protected
- Clinical trials are scientifically robust and ethically conducted
- The data generated are reliable and fit for purpose

### **Do I need GCP training?**

Yes. All individuals involved in the conduct of clinical research must be appropriately trained to carry out their roles.

This requirement is set out in the Research Governance Framework for Health and Social Care (2005) and remains a key expectation under the updated ICH GCP principles.

ICH GCP E6(R3) reinforces that:

Individuals involved in a trial must be qualified by education, training and experience to perform their delegated responsibilities.

NHS Greater Glasgow & Clyde recommends that GCP training is refreshed every 2 years to ensure staff remain up to date with current guidance and best practice.

### **How do I get GCP training?**

NIHR CRN have developed GCP training courses which have a practical focus, with the key aim that participants know what to do to practise excellent GCP when they return to their workplace to ensure the rights, safety and well-being of patients and the quality of the research data. [Good Clinical Practice \(GCP\) | NIHR](#)

Additional face-to-face GCP training and clinical research courses can be found using the following link at NHS Research Scotland website: [Course Browse | NHS Research Scotland | NHS Research Scotland](#)

*NHSGCCs SOP on GCP Non-Compliance (51.008) - [sop51-008 v5-0.pdf](#)*

# Research Passport

## What is the Research Passport?

A Research Passport is the mechanism for Higher Education Institutes (HEI) staff to obtain an Honorary Research Contract (HRC) or Letter of Access (LOA) when they propose to carry out research in the NHS.

The Research Passport system provides:

- One set of checks on a researcher conducting research in the NHS.
- One standard form completed by the researcher and his/her employer, and validated by an NHS organisation.
- A completed Research Passport which is presented to all the relevant NHS organisations.

Faster study start-up.

## Who does not need a Research Passport?

- You will not need a Research Passport or an Honorary Research Contract if:
- You are employed by an NHS organisation (If you are looking to do research in a different health board, you would require to complete an NHS to NHS proforma to gain a Letter of access); or
- You are an independent contractor (e.g. GP) or employed by an independent contractor; or
- You have an honorary clinical contract with an NHS Trust e.g. clinical academics. In this situation if you wanted to research in another NHS Trust you would need to apply to their R&I department directly for a Letter of Access; or
- You are a student on a healthcare placement.



## Who needs a Research Passport?

If you are not in any of the above categories and you have no contractual relationship with the NHS, you will need a Research Passport if you are proposing to carry out research in the NHS. A Research Passport may be project-specific or may be valid for a period of three years for a number of projects.

## How do I get a Research Passport?

1. Read the [guidance for completing the Research Passport form](#)
2. Contact the R&I department in your lead NHS Trust to confirm which pre-engagement checks you need.
3. Complete the necessary [occupational health assessments](#) and/or a criminal record disclosure application.
4. Complete sections 1–3 of the Research Passport form.
5. Ask your University line manager/supervisor to complete section 4.
6. Send form, checklist coversheet and documentary evidence to your HR Division. For University of Glasgow's contact details can be found here: <https://www.gla.ac.uk/myglasgow/pod/contact/#d.en.503126>
7. The HR Division/Board of Graduate Studies will sign off their part of the form and return it to you.
8. Once the form has been authorised by one NHS organisation it becomes a valid Research Passport that you can provide to other NHS organisations when you require an Honorary Research Contract or Letter of Access.

You may only start your work within an NHS Health board when that Health board has issued you with either an Honorary Research Contract or a Letter of Access. Please note that the Research Passport is only the mechanism to apply for these, it is not in itself permission to work in an NHS Health board.

## Honorary Clinical Contract

An honorary clinical contract within NHSGGC is a formal agreement issued to clinical academics who are not directly employed by the NHS but who need access to NHS patients for clinical purposes. This is separate to a Honorary research contract. For more information or to get a Honorary clinical contract please contact [ggc.medicalhonorary@nhs.scot](mailto:ggc.medicalhonorary@nhs.scot)

*NHSGGC SOP on Research Passports (52.005) - [sop52-005 v6-0.pdf](#)*

# Modifications

What are modifications?

Modification (formally known as amendments) are changes made to your study after a REC favourable opinion has been granted. These Modifications can be substantial, Modification of an important detail (MOID) or minor modifications.

**For all studies, it is the responsibility of the Sponsor (NHSGGC) to determine whether a modification is substantial therefore, you must contact the R&I office to discuss any changes you wish to make. R&I will then confirm whether the changes are a substantial/ MOID or minor modification.**

What are substantial modifications?

Substantial modifications are changes to the study that are likely to have a significant impact on one or more of the following:

- The safety, rights, or wellbeing of participants
- The scientific value or validity of the research
- The conduct or management of the study
- The quality or safety of any investigational medicinal product (IMP) or device

**Examples of substantial modifications include:**

- Changes to the study design, methodology, or background information that may affect scientific validity
- Changes to participant procedures or study interventions
- Changes impacting the risk–benefit balance or participant safety
- Significant updates to participant-facing documents (e.g. PIS, consent forms, questionnaires, invitation letters)
- Change of Sponsor or Sponsor's legal representative
- Appointment of a new Chief Investigator
- Changes to insurance or indemnity arrangements
- Temporary halt and restart of a study for safety reasons
- Changes to the definition of end of study
- Any other change with a significant impact on regulatory approvals or study integrity

What are modification of an important detail (MOID)?

MOID modifications are changes that require notification and oversight, but are not considered substantial. These typically relate to updates that may affect how the study is run locally but do not significantly impact participant safety or scientific validity.

**Examples of MOID modifications include:**

- Changes to the research team, including additions or removals of staff (excluding Chief Investigator changes)
- Appointment of a new Principal Investigator at an NHS/HSC location
- Addition of new NHS/HSC locations
- Changes to local study procedures or delivery arrangements

- Updates to supporting documentation that do not affect participant safety or study design
- Changes requiring R&D approval but not REC approval

### What is a Minor Modification?

Minor modifications are administrative or low-impact changes that do not affect participant safety, scientific value, or study conduct in a significant way.

### **Examples of minor modifications include:**

- Correction of typographical errors or formatting issues
- Updates to contact details or administrative information
- Minor clarifications to study documents with no impact on meaning
- Changes to internal documentation (e.g. data collection tools)
- Changes to logistical arrangements, such as sample storage or transport
- Updates to the Investigator's Brochure where there is no change to risk–benefit
- Changes to funding arrangements with no impact on study delivery
- Changes to the study end date where no other significant changes are introduced

### **Preparing a modification**

To initiate a modification, please complete the [modification tool](#), referring to the 'Glossary of modification Options' tab for guidance. Submit the completed tool along with any supporting documents, please make sure any patient facing documents are both clean and tracked versions, to the R&I Coordinator or Facilitator for review.

You should make sure the versions and dates are updated on all documentation. Additionally, modifications can have an impact on funding and contracts which might implicate additional costs to your study (e.g. Additional NHS costing sheets and amendments to contracts). You're R&I coordinator/facilitator will highlight any changes needed to the costs and contracts.

Once the R&I coordinator/facilitator has reviewed the documents and locked the modification tool, a Sponsor modification decision email will be sent allowing you to submit your modification to IRAS.

### **Submitting modifications**

Modifications must be submitted via the following link: <https://www.myresearchproject.org.uk/help/hlpamendments.aspx#Online-Submission>. Please note that this is a separate online submission process from your initial IRAS application. You will need to create a new IRAS modification account to proceed.

- Click create new modification
- Put in the IRAS ID and verify – This will bring up your study and you can check this with the title.

- Populate the fields with information from the modification tool.
- Add the documents from the sponsor decision email (this will have to be done individually, make sure the versions and date are correct)

**Once you click submit your modification is automatically sent to relevant approving bodies. You will get an automatic reply (keep this response as you will need to inform location if your study is multi-centre)**

For more information and help on submitting a modification using the following link:  
<https://www.myresearchproject.org.uk/help/hlpamendments.aspx>

## Local R&I Modification Approval

Once the modification has been submitted you need to notify all participating locations of the modification.

### Notifying participating locations

- Single Centre Studies
  - In Scotland, single centre study modification shall be sent directly to R&I office and research team at the participating organisation as per the information in the Modification Tool
- Multicentre Studies
  - For multicentre studies, modifications should be sent to [gram.nrspcc@nhs.scot](mailto:gram.nrspcc@nhs.scot) for Scottish locations. For English and Welsh locations, a [template-based](#) email should be submitted directly to the relevant R&D, with the research team copied in. You can find contact details for other R&D offices using the following link: [R&D Contacts Directory - NHS R&D Forum](#).

Once R&I has been notified of the modification, they will review it and issue local R&I approval for Category A and applicable Category B modification. Category B modification refer to changes in a research project that impact only specific participating NHS/HSC organisations, rather than all locations involved in the study. For Category C modifications, local approval is not required; these can be implemented once all relevant approvals such as REC and HRA are in place

**Please note: You must not implement any modification without notifying R&I, unless urgent safety measures have been taken. Urgent safety measures should be notified to your R&I Sponsor representative as soon as possible.**

*NHSGGC SOP on Modification review & Approval - [sop51-021 v6-0.pdf](#)*

## Participating Location Set up

For multi-center projects with no Project Management (PM) support, it is the CI's responsibility to set up participating locations ready for local management approval.

### Notifying participating locations

Local Information Pack (LIP) [email template](#) must be completed for each location. The documents table should also be completed, and a list of the relevant study documents must be attached:

- All patient facing documents (including clean and tracked versions)
- Contracts (Relevant model agreement e.g. Outline OID or mNCA where applicable)
- IRAS form
- Delegation Log
- SoECAT or Schedule of Events (SofE)
- Any other relevant approvals e.g. PBPP, Caldicott, CAG
- Any modifications

Once your template is completed you can send these to all of the participating locations and include the PI's and the local R&D offices

- For England, Wales & Northern Ireland, you will need to send an email to each individual location. How to find the contacts will be on this link: [R&D Contacts Directory - NHS R&D Forum](#) just type in the trust name and their email will be there.
- For Scotland send 1 email to [gram.nrspcc@nhs.scot](mailto:gram.nrspcc@nhs.scot). This is the Permissions Coordinating Centre for Scotland. They make sure your documents are sent to the correct R&D departments in Scotland.

### Contracts review

Once a location has reviewed and localised the contract, it must be submitted to the Sponsor for review and final authorisation/signature.

- OID - The local study team will localise the OID, which must then be reviewed and authorised by the Sponsor. The OID must be signed off by the local R&D department. (A common error is for the PI to sign the OID; however, this is incorrect, as sign-off must be completed by the local R&D department.)
- mNCA – The location will review and localise the mNCA before returning it to the Sponsor for review and initiation of signatures. Signatures are completed electronically via DocuSign. The Sponsor will require the signatory details (name and email address) for both the location contact and the local PI.

## Participating Location Checklist

A [checklist](#) should be used for each location to confirm that all requirements are in place prior to issuing Green for Go (location opening to recruitment). While the checklist can be adapted to suit the specific needs of your study, it is a useful tool for tracking completed activities and identifying any outstanding actions.

As part of the checklist, you must obtain the following:

- Training logs (where applicable). A training log is required for studies using an eCRF system (e.g. REDCap).
- Principal Investigator's (PI) CV and GCP certificate (dated within the last two years).
- Signed delegation log.
- [Protocol approval page](#). This must be signed by the PI to confirm they have reviewed the study and agree to conduct it in accordance with the protocol.

## Green for Go

The location will provide a local management approval letter or Confirmation of Capacity and Capability (C&C) once all local checks have been completed. The Green for Go email formally notifies the local study team and PI that the location is fully initiated and may begin recruitment and trial activities. This can only be issued once all required steps on the checklist have been completed. When issuing the [Green for Go email](#), it should be sent to the PI and the R&D contact should be copied in.

## NIHR Portfolio & CPMS

The NIHR Research Delivery Network (RDN) Portfolio is a national collection of research studies that meet specific eligibility criteria. The NIHR provides a [list of approved funders](#) (such as major charities, government bodies, NIHR itself, and certain industry routes) whose funding allows studies to be considered for portfolio adoption. Studies included in the portfolio are eligible for NIHR support to assist with their delivery.

The Central Portfolio Management System (CPMS) is the national, cloud-based system used to manage the portfolio. It holds information on all NIHR portfolio studies.

Participating locations may ask whether a study has been adopted into the NIHR portfolio. If a study is funded by an organisation on the NIHR approved list, it is considered eligible and can be adopted. If the funder is not on this list, the study cannot be added to the NIHR portfolio.

Where applicable, the sponsor will create a CPMS record, and the study will then be automatically added to the NIHR portfolio.

*NHSGGC SOP on Location Set up – Green for Go Process - [sop56-001\\_v9-0.pdf](#)*

## Safety Reporting

To ensure compliance with Good Clinical Practice (GCP) E6(R3), the Research Governance Framework, and the Medical Devices Regulations 2002, Chief and Principal Investigators undertaking non-CTIMP clinical studies are responsible for the identification, documentation, and timely reporting of Serious Adverse Events (SAEs).

This responsibility forms part of the broader requirement under ICH GCP to ensure appropriate safety oversight, robust risk management, and the ongoing protection of research participants throughout the study lifecycle.

In research a Serious Adverse Event (SAE) is defined as an untoward occurrence that:

- (a) results in death;
- (b) is life-threatening;
- (c) requires hospitalisation or prolongation of existing hospitalisation;
- (d) results in persistent or significant disability or incapacity;
- (e) consists of a congenital anomaly or birth defect; or
- (f) is otherwise considered medically significant by the investigator.

An SAE occurring in a research participant must be reported to the main REC (i.e. the REC that gave a favourable opinion of the study) where in the opinion of the investigator it is:

- “Related” – that is, it resulted from administration of any of the research procedures, and
- “Unexpected” – that is, the type of event is not listed in the protocol as an expected occurrence.

Reports of related and unexpected SAEs should be submitted within 15 calendar days of the PV Office becoming aware of the event, using the ‘Non-CTIMP safety report to REC form’ published on the NHS Health Research Authority website. <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/>

The Coordinator of the main REC will acknowledge receipt of safety reports within 30 days.

*NHSGGC SOP on Safety Reporting (55.004) - [sop55-004\\_v5-0.pdf](#)*

## Audit

Audit is a systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled. However most importantly, the purpose of audit is to support and advise investigators with their studies and to promote good research within the Trust.

Audits of NHSGGC non-CTIMP study portfolio will consist of the following types of audit:

- Self-assessment audit
- GCP Non-compliance audit

The purpose of study audit is to verify that systems are in place to ensure:

- The rights and well-being of human subjects are protected
- To collect the study data as stated in the protocol
- The conduct of the study is in compliance with the approved study protocol/modifications, GCP and the Research Governance Framework and with the applicable regulatory requirements.

### The Audit Process

Audits can be “face to face” or if this is not possible to conduct an audit in person a remote audit may be carried out.

The auditor will contact the Chief/Principal Investigator to notify them of the audit meeting, provide an agenda and arrange a mutually agreeable meeting time. The agenda will outline a list of the study documentation which should be available for the visit. This will include the documentation required in the Trial Master File (TMF). The following documents, but not limited to, will be checked:

- Regulatory approvals
- Agreements
- Delegation Log
- Recruitment log
- Consent Forms
- Honorary contracts and GCP Training
- Safety Reporting
- Study Data Capture



# End of study

## When is a project complete?

The completion of a project should be defined in the protocol. In most cases, completion will be the date of the last patient's last visit (LPLV) or the completion of any patient follow-up and data collection.

## What should I do when my project has completed?

### 1. Communicate completion to relevant bodies and authorities

For all projects, a 'Declaration of End of Study' form must be completed and sent to the REC that granted a favourable ethical opinion for the project. This form can be found online: [Declaration-end-study-form-v1-6\\_YiR7Sfb.odt](#)

The R&D office should be copied into this notification.

For studies that have HRA and HCRW approval, but did not require REC review, you will need to notify HRA directly at [approvals@hra.nhs.uk](mailto:approvals@hra.nhs.uk).

### 2. Final analysis of data and locking of the project database (if applicable)

### 3. Complete all financial obligations

Any outstanding invoices payable or to be raised should be dealt with and arrangements in place for providing treatment to participants after completion (if agreed).

### 4. Writing of final project reports, dissemination and publication of findings

Once you have completed the end of study form you must submit your Final Report within 12 months of the conclusion of the end of study. This is completed online using the following link: [Submit your Final Report - Health Research Authority](#)

## **5. Archiving of documentation**

After receiving confirmation of study closure from the REC or HRA your coordinator/facilitator will send the archiving form the CI to complete. Participating locations are responsible for archiving their Investigator Site Files (ISFs) using local procedures and must return a completed Non-CTIMP Site Archiving Checklist to the Information Officer. If locations do not respond within three months, the issue is escalated. For more information contact your coordinator/facilitator.

### **What should I do when my project has not completed on time?**

Occasionally projects do not finish recruiting or following-up patients within the time specified in the REC-approved protocol. An extension to the study end date is normally considered to be a minor modification.

For an extension please get in contact with your R&I coordinator/facilitator.

**It is your responsibility to notify the relevant bodies and authorities of the end of the study, and to ensure that all participating locations are notified of archiving.**

*NHSGGC SOP on End of study procedures (51.005) - [sop51-005 v4-0.pdf](#)*

## NHSGGC R&I Tips

- Inform us immediately if you have a concern over the sponsorship of your research.
- Use the [Strategic form](#) and the [Costing sheet](#) are submitted to R&I via our generic grants email address: [ggc.randigrantapplications@nhs.scot](mailto:ggc.randigrantapplications@nhs.scot) to ensure your study is allocated with an R&I reference number.
- Be sure to include your R&I reference number in the subject line on all correspondence with R&I.
- When emailing R&I your documents please make sure they are all sent in 1 package, including any tracked changes versions of your documents.
- Allow at least **20 working days** from submitting your application before the costing can be made available.
- If you are asked for further information or documents, provide these as soon as possible.
- For large projects, it is recommended to designate a single point of contact. In the case of multi-centre studies, appointing a Project Manager is strongly advised. If a Project Manager is not assigned, the Chief Investigator (CI) will serve as the primary point of contact.
- Inform R&I of any change of CI/PI and staff absence's including moving/leaving current post. For any NHSGGC staff changes/additions please complete the change of study team form.
- Throughout the process and after approval, it is recommended that all versions of project documentation are saved, including tracked changes.
- As a CI if you do not have a Project Manager for a multi-centre study, you are responsible for contacting participating locations and following the Project Management SOPs found using the following link: [Glasgow Clinical Trials Unit](#)

## Useful Links and Resources:

NHSGGC R&I Sponsor SOPs [www.glasgowctu.org/Home/forms/51-nhs-gg-and-c-sponsor-r-and-i/](http://www.glasgowctu.org/Home/forms/51-nhs-gg-and-c-sponsor-r-and-i/)

NHSGGC contacting wider R&I team [www.nhsggc.scot/staff-recruitment/staff-resources/research-and-innovation/](http://www.nhsggc.scot/staff-recruitment/staff-resources/research-and-innovation/)

R&D Contacts Directory [R&D Contacts Directory - NHS R&D Forum](#)

Integrated Research Application System (IRAS) <https://www.myresearchproject.org.uk/>

IRAS Modifications [www.myresearchproject.org.uk/help/hlpamendments.aspx#Online-Submission](http://www.myresearchproject.org.uk/help/hlpamendments.aspx#Online-Submission)

Health Research Authority (HRA) <http://www.hra.nhs.uk/>

HRA Decision Tool  
<http://www.hra-decisiontools.org.uk/research/>

NHSGGC CRF Training Courses [www.nhsresearchscotland.org.uk/research-in-scotland/facilities/clinical-research-facilities/glasgow-research-facility/training-and-courses/browse](http://www.nhsresearchscotland.org.uk/research-in-scotland/facilities/clinical-research-facilities/glasgow-research-facility/training-and-courses/browse)

Human Tissue (Scotland) Act 2006 (HTA 2006) [Human Tissue \(Authorisation\) \(Scotland\) Act 2019](#)

Human Fertilisation and Embryology Authority (HFEA) [HFEA: UK fertility regulator](#)

Data Protection  
<https://www.gov.uk/data-protection/the-data-protection-act>

Research Governance Framework for Health and Social Care: v3.3, 2017.  
[www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/](http://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/)

Public Benefit and Privacy Panel (PBPP)  
[www.informationgovernance.scot.nhs.uk/pbp-phsc/home/for-applicants/](http://www.informationgovernance.scot.nhs.uk/pbp-phsc/home/for-applicants/)

Confidentiality Advisory Group (CAG) (English locations)  
<http://www.hra.nhs.uk/resources/confidentiality-advisory-group/>

Administration of Radioactive Substances Advisory Committee (ARSAC)  
[www.gov.uk/government/publications/arsac-notes-for-guidance](http://www.gov.uk/government/publications/arsac-notes-for-guidance)

## Appendix A – Defining Research

| RESEARCH                                                                                                                                                                                                                                                                                          | SERVICE EVALUATION                                                                                                                                                                                                                  | CLINICAL/ NON-FINANCIAL AUDIT                                                                                                                                                                                                      | USUAL PRACTICE<br>(in public health including health protection)                                                                                                                                         |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The attempt to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods* including studies that aim to generate hypotheses as well as studies that aim to test them, in addition to simply descriptive studies.                                   | Designed and conducted solely to define or judge current care.                                                                                                                                                                      | Designed and conducted to produce information to inform delivery of best care.                                                                                                                                                     | Designed to investigate the health issues in a population in order to improve population health<br>Designed to investigate an outbreak or incident to help in disease control and prevention             |
| Quantitative research – can be designed to test a hypothesis as in a randomised controlled trial or can simply be descriptive as in a postal survey.<br>Qualitative research – can be used to generate a hypothesis, usually identifies/explores themes.                                          | Designed to answer: “What standard does this service achieve?”                                                                                                                                                                      | Designed to answer: “Does this service reach a predetermined standard?”                                                                                                                                                            | Designed to answer: “What are the health issues in this population and how do we address them?”<br>Designed to answer: “What is the cause of this outbreak or incident and how do we manage it?”         |
| Quantitative research - addresses clearly defined questions, aims and objectives.<br>Qualitative research – usually has clear aims and objectives but may not establish the exact questions to be asked until research is underway.                                                               | Measures current service without reference to a standard.                                                                                                                                                                           | Measures against a standard.                                                                                                                                                                                                       | Systematic, quantitative or qualitative methods may be used.                                                                                                                                             |
| Quantitative research – may involve evaluating or comparing interventions, particularly new ones.<br>However, some quantitative research such as descriptive surveys, do not involve interventions.<br>Qualitative research – seeks to understand better the perceptions and reasoning of people. | Involves an intervention in use only.<br>The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/ service user preference. | Involves an intervention in use only.<br>The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/service user preference. | Involves an intervention in use only.<br>Any choice of intervention, treatment, care or services is based on best public health evidence or professional consensus.                                      |
| Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care. May involve data collected from interviews, focus groups and/or observation.               | Usually involves analysis of existing data but may also include administration of interview(s) or questionnaire(s).                                                                                                                 | Usually involves analysis of existing data but may include administration of simple interview or questionnaire.                                                                                                                    | May involve analysis of existing routine data supplied under license/agreement or administration of interview or questionnaire to those in the population of interest. May also require evidence review. |
| Quantitative research – study design may involve allocating patients/service users/healthy volunteers to an intervention.<br>Qualitative research – does not usually involve allocating participants to an intervention.                                                                          | No allocation to intervention: the care professional and patient/ service user have chosen intervention before service evaluation.                                                                                                  | No allocation to intervention: the care professional and patient/service user have chosen intervention before audit.                                                                                                               | No allocation to intervention.                                                                                                                                                                           |
| May involve randomisation.                                                                                                                                                                                                                                                                        | No randomisation.                                                                                                                                                                                                                   | No randomisation.                                                                                                                                                                                                                  | May involve randomisation but not for treatment/ care/ intervention.                                                                                                                                     |
| Normally requires REC review but not always. Refer to <a href="http://hra-decisiontools.org.uk/ethics/">http://hra-decisiontools.org.uk/ethics/</a> for more information.                                                                                                                         | Does not require REC review.                                                                                                                                                                                                        | Does not require REC review.                                                                                                                                                                                                       | Does not require REC review.                                                                                                                                                                             |

Published October 2017 © Health Research Authority 2017. Copyright and other intellectual property rights in this material belong to the HRA and all rights are reserved. The HRA authorises UK healthcare organisations to reproduce this material for educational and non-commercial use.

# Glossary - Commonly Used Research Abbreviations and Terms

|              |                                                                                                                                                                                                                                                                                                                                                                    |
|--------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| ABPI         | Association of the British Pharmaceutical Industry: A trade association for UK pharmaceutical companies                                                                                                                                                                                                                                                            |
| ADR          | Adverse Drug Reaction (also known as AR)                                                                                                                                                                                                                                                                                                                           |
| AE           | Adverse Event                                                                                                                                                                                                                                                                                                                                                      |
| Modification | A written description of a change or formal clarification. Substantial modification to protocol, participant information/consent require REC and R&D approval, MOID & Minor modifications should be 'notified' to REC and R&D                                                                                                                                      |
| AMRC         | Association of Medical Research Charities                                                                                                                                                                                                                                                                                                                          |
| AR           | Adverse Reaction (also known as ADR)                                                                                                                                                                                                                                                                                                                               |
| ARSAC        | Administration of Radioactive Substances Advisory Committee: Research studies wishing to administer radioactive medicinal products to human subjects need to obtain ARSAC approval before NHS R&D approval                                                                                                                                                         |
| ASR          | Annual Safety Report: For studies involving the use of an Investigational Medicinal Product, this is the annual report which must be submitted to the MHRA detailing all SUSARs and SARs that have occurred in subjects on that study in the past year                                                                                                             |
| ATMP         | Advanced Therapy Medicinal Products                                                                                                                                                                                                                                                                                                                                |
| BP           | Blood pressure                                                                                                                                                                                                                                                                                                                                                     |
| BRC          | Biomedical Research Centre: larger centre covering a number of topics with facilities and research active clinicians/academics/research nurses to run clinical projects                                                                                                                                                                                            |
| BRU          | Biomedical Research Unit: topic-focused centre which usually combines facilities and research active clinicians/academics/research nurses to run clinical projects, e.g. respiratory BRU                                                                                                                                                                           |
| C/O          | Complaints of                                                                                                                                                                                                                                                                                                                                                      |
| CA           | Competent Authority: organisation approving the testing of new drugs/devices or approving the marketing licences, in the UK this is the MHRA                                                                                                                                                                                                                       |
| CC           | Coordinating Centre                                                                                                                                                                                                                                                                                                                                                |
| CCRN         | Comprehensive Clinical Research Network                                                                                                                                                                                                                                                                                                                            |
| CF           | Consent Form (also ICF, Informed Consent Form)                                                                                                                                                                                                                                                                                                                     |
| CFR          | Code of Federal Regulations (US)                                                                                                                                                                                                                                                                                                                                   |
| CI (i)       | Chief Investigator: The lead investigator with overall responsibility for the research. In a multi-site study, the CI has coordinating responsibility for research at all sites. The CI may also be the PI at the site in which they work. In the case of a single-site study, the CI and the PI will normally be the same person and are referred to as PI.       |
| CI (ii)      | Coordinating investigator                                                                                                                                                                                                                                                                                                                                          |
| CLRN         | Comprehensive Local Research Network: CLRNs are the primary vehicle for providing infrastructure to support study involvement at local NHS Trusts. There are 25 in England.                                                                                                                                                                                        |
| COREC        | Central Office for Research Ethics Committees (replaced in 2007 by NRES)                                                                                                                                                                                                                                                                                           |
| CRA          | Clinical Research Associate: usually a commercially employed person supporting the management of clinical studies, helps with obtaining R&D approval, site initiation, study monitoring and close out                                                                                                                                                              |
| CRF (i)      | Case Report Forms: data collection tools provided by a sponsor on which the clinical data is recorded for each participant, such as weight, lab results, symptoms                                                                                                                                                                                                  |
| CRF (ii)     | Clinical Research Facility: hospital-like facility with consulting rooms, standard patient beds, ward medical equipment, research nurses supporting only research                                                                                                                                                                                                  |
| CRN          | Clinical Research Network                                                                                                                                                                                                                                                                                                                                          |
| CRO          | Clinical Research Organisation or Contract Research Organisation: A person or an organisation (commercial, academic or other) contracted by the sponsor to perform one or more of a sponsor's trial-related duties and functions                                                                                                                                   |
| CSAG         | Clinical Studies Advisory Group                                                                                                                                                                                                                                                                                                                                    |
| CSG          | Clinical Studies Group                                                                                                                                                                                                                                                                                                                                             |
| CSP          | Coordinated System for gaining NHS Permissions: Standard process for adoption onto NIHR Portfolio of Studies in order to access NIHR CRN Support and funding; streamlines the process for gaining NHS permissions by collating the information for global and local approvals; researchers initiate this in IRAS by completing and submitting CSP Application Form |
| CTA (i)      | Clinical Trials Administrator: person providing coordinating/secretarial support for running clinical studies                                                                                                                                                                                                                                                      |
| CTA (ii)     | Clinical Trials Agreement: contract between the legal Sponsor and the hosting research sites                                                                                                                                                                                                                                                                       |
| CTA (iii)    | Clinical Trials Associate (similar to CRA): person involved in the management of a study from initiation, through conduct/monitoring to close-out                                                                                                                                                                                                                  |
| CTA (iv)     | Clinical Trials Authorisation: The regulatory approval for a clinical trial of a medicinal product issued by the MHRA                                                                                                                                                                                                                                              |

|                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CTAAC           | Clinical Trials Advisory and Awards Committee                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| CTD             | Clinical Trial Document                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| CTIMP           | Clinical Trial of an Investigational Medicinal Product                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| CTU             | Clinical Trials Unit: Design and manage CTIMPs, sometimes in specialist clinical areas, such as Cancer, or types of trial, such as RCTs                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| CV              | Curriculum Vitae                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| D&V             | Diarrhoea and Vomiting                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| DCF             | Data Collection Form                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| DeNDRoN         | Dementias and Neurodegenerative Diseases Research Network                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| DH              | Department of Health (for England)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| DIPEX           | Database of Individual Patient Experience – the DIPEX website has a range of open source videos of real patient experiences <a href="http://www.healthtalkonline.org">www.healthtalkonline.org</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| DNA             | Did not attend                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| DPA             | Data Protection Act                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| DQ              | Data query                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| DRN             | Diabetes Research Network                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| DSMB            | Data and Safety Monitoring Board: An independent committee composed of clinical research experts and community representatives that reviews data whilst a clinical trial is in progress to ensure that participants are not being exposed to undue risk                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| ECG             | Electrocardiogram                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| ECMC            | Experimental Cancer Medicine Centre                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| EM              | Experimental Medicine                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| EMA             | The European Medicines Agency: A body of the European Union which has responsibility for the protection and promotion of public health through the evaluation and supervision of medicines for human use                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| EU              | European Union                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| EudraCT         | European Clinical Trials Database: A database of all clinical trials in Europe, held since 1994 in accordance with EU directive 2001/20/EC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| FAQ             | Frequently Asked Questions                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| FDA             | Food and Drug Administration: the Competent Authority in the United States, giving authorisation to conduct clinical trials and issuing marketing licences                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| GAfREC          | Governance Arrangements for Research Ethics Committees                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| GCP             | Good Clinical Practice: A specific internationally recognised version of this is ICH-GCP (see below)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| GLP             | Good Laboratory Practice: standard for laboratories involved in pre-clinical analyses (e.g. animal, in vitro); does not apply to Laboratories analysing samples from clinical trials involving humans                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| GMP             | Good Manufacturing Practice: quality assurance standard for producing IMP, medicinal products                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| GTAC            | Gene Therapy Advisory Committee: the ethics committee for clinical studies using genetically modified products; usually no REC approval required                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| HEI             | Higher Education Institution                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| HFEA            | Human Fertilisation and Embryological Authority                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| HRC             | Honorary Research Contract                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| HTA             | Human Tissue (Scotland) Act 2006 or Human Tissue Authority                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| HTA (Programme) | Health Technology Assessment – one of the NIHR research funding streams                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| IB              | Investigator's                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| ICH-GCP         | International Conference on Harmonisation (Europe, USA, and Japan): Defined standards for the terminology, design, conduct, monitoring, recording, analysis and reporting of a study. These standards give assurance that the reported results are accurate and credible and that the rights, integrity and confidentiality of all study participants have been protected throughout the study. Section E6 of ICH defines principles of Good Clinical Practice (referred to as ICH-GCP). Research teams on CTIMPs in the UK must follow GCP requirements as detailed in MfHU (CT) Statutory Instruments; all non-CTIMP studies conducted within the NHS adhere to GCP according to Research Governance Framework |
| IDMC            | Independent Data Monitoring Committee                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| IMP             | Investigational Medicinal Product: an unlicensed new drug, or an existing drug tested outside its licence, or existing drugs tested against each other for their efficacy/safety. The MHRA provide an algorithm to establish whether a study is a CTIMP: see Resource 2 or the MHRA website (provided on p67) <a href="http://www.mhra.gov.uk/home/groups/-unit1/documents/websiteresources/con009394.pdf">http://www.mhra.gov.uk/home/groups/-unit1/documents/websiteresources/con009394.pdf</a>                                                                                                                                                                                                                |
| IND             | Investigational New Drug: sometimes used instead of IMP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Indemnity       | Compensation for damage, loss or injury                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| Investigator    | Researcher conducting the (clinical) study, those researchers leading the team are referred to as CI or PI                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |



|                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|-------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| IRAS                          | Integrated Research Application System: A single, web-based system for completing applications for the permissions and approvals required for health and social care research in the UK. The various applications can be printed or submitted for this single system (includes REC, R&D, MHRA, GTAC, NIGB, ARSAC)                                                                                                                                                         |
| IRB                           | Independent Review Boards: US equivalent of authorised REC                                                                                                                                                                                                                                                                                                                                                                                                                |
| IRMER                         | Ionising Radiation Medical Exposure Regulations: part of NHS R&D approval, usually done by the local hospital experts                                                                                                                                                                                                                                                                                                                                                     |
| ISF                           | Investigator Site File: A file designed for use in organising and collating all essential documentation required to conduct a study in accordance with the principles of GCP and the applicable regulatory requirements (e.g. REC approval letter/correspondence, MHRA approval, blank CRF, staff CVs, delegation of duties log etc.)                                                                                                                                     |
| ISRCTN                        | International Standard Randomised Control Trial Number: A simple numeric system for the identification of randomised controlled clinical trials worldwide. Allows the identification of trials and provides a unique number that can be used to track all publications and reports resulting from each trial; can be obtained from <a href="http://www.isrctn.org">www.isrctn.org</a> or <a href="http://www.controlledtrials.com/mrct">www.controlledtrials.com/mrct</a> |
| LRN                           | Local Research Network                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| MCA                           | Mental Capacity Act                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| mCIA                          | model Clinical Investigation Agreement: for medical devices, covers the running of the study, not design of prototype or design of protocol; standard template for the UK (use is not obligatory)                                                                                                                                                                                                                                                                         |
| MCRN                          | Medicines for Children Research Network                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| mCTA                          | model Clinical Trial Agreement: for IMP studies with commercial sponsor/CRO conducted; standard template for the UK (use is not obligatory)                                                                                                                                                                                                                                                                                                                               |
| MfHU (CT)                     | Medicines for Human Use (Clinical Trials) Regulations: SI 2004:1031 and subsequent amendments 2006:1928, 2006:2984, 2008:941, 2009:1164 and 2010:1882 are the UK Statutory Instruments translating EU directives 2001/20/EC and 2005/28/EC into UK law, laying down the legal requirements for conducting CTIMPs in the UK                                                                                                                                                |
| MHRA                          | Medicines and Healthcare products Regulatory Agency: The UK Competent Authority (CA) and licensing authority for medicines and medical devices. It replaced both the Medical Devices Agency (MDA) and the Medicines Control Agency (MCA) in April 2003                                                                                                                                                                                                                    |
| MHRN                          | Mental Health Research Network                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| mNCA                          | model Non-Commercial Agreement: for clinical research studies; standard template for the UK (use is not obligatory)                                                                                                                                                                                                                                                                                                                                                       |
| Monitor                       | The person designated by the sponsor to perform site visits and conduct the monitoring process; e.g. check whether there are any deviations from the protocol and that all source data was transferred into the Case Report Forms correctly                                                                                                                                                                                                                               |
| MRC                           | Medical Research Council                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Multi Centre Study            | A study conducted according to a single protocol but carried out at more than one site and by more than one investigator; one CI oversees several local PIs                                                                                                                                                                                                                                                                                                               |
| NCRN                          | National Cancer Research Network                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| ND                            | Not done                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| NHS                           | National Health Service                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| NICE                          | National Institute for health and Clinical Excellence (decides which drugs are accepted into NHS treatment)                                                                                                                                                                                                                                                                                                                                                               |
| NIGB                          | National Information Governance Board for Health and Social Care Ethics and Confidentiality Committee                                                                                                                                                                                                                                                                                                                                                                     |
| NIHR                          | National Institute for Health Research: established by Department of Health for England in 2006 to provide the framework through which DH will position, manage and maintain the research, research staff and infrastructure of the NHS in England as a virtual national research facility                                                                                                                                                                                |
| NIHR CRN CC                   | National Institute for Health Research Clinical Research Network Coordinating Centre                                                                                                                                                                                                                                                                                                                                                                                      |
| NIHR IS                       | National Institute of Health Research Information Systems                                                                                                                                                                                                                                                                                                                                                                                                                 |
| NIMP (or non-IMP)             | Non-Investigational Medicinal Product: product used alongside IMP but not directly under investigation in the research study, e.g. a challenge agent                                                                                                                                                                                                                                                                                                                      |
| NK                            | Not known                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| NOCRI                         | National Office for Clinical Research Infrastructure                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Non-substantial modifications | Changes to the details of a study that have no significant implications for the subjects, the conduct, the management or the scientific value of the study (sometimes referred to as administrative modifications).                                                                                                                                                                                                                                                       |



|                   |                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| NRES              | National Research Ethics Service: umbrella organisation responsible for all REC across the UK (replaced COREC in 2007)                                                                                                                                                                                                                                                                                                              |
| OSCHR             | The Office for Strategic Coordination of Health Research (UK wide)                                                                                                                                                                                                                                                                                                                                                                  |
| PCF               | Patient/Participant Consent Form                                                                                                                                                                                                                                                                                                                                                                                                    |
| PCRN              | Primary Care Research Network                                                                                                                                                                                                                                                                                                                                                                                                       |
| PCT               | Primary Care Trust                                                                                                                                                                                                                                                                                                                                                                                                                  |
| PI                | Principal Investigator: The lead person at a single site designated as taking responsibility within the research team for the conduct of the study                                                                                                                                                                                                                                                                                  |
| PIAG              | Patient Information Advisory Group (now NIGB)                                                                                                                                                                                                                                                                                                                                                                                       |
| PIC               | Participant Identification Centre: NHS or other organisation which only identifies participants from a database etc., but recruitment/receiving consent and study conduct are managed elsewhere                                                                                                                                                                                                                                     |
| PIS               | Participant or Patient Information Sheet: An information leaflet given to those who have been invited to participate in a research study. The sheet is designed to provide the potential participant with sufficient information to allow that person to make an informed decision on whether or not they want to take part                                                                                                         |
| PPI               | Patient and Public Involvement                                                                                                                                                                                                                                                                                                                                                                                                      |
| QA                | Quality Assurance                                                                                                                                                                                                                                                                                                                                                                                                                   |
| QC                | Quality Control                                                                                                                                                                                                                                                                                                                                                                                                                     |
| QLQ               | Quality of Life Questionnaire                                                                                                                                                                                                                                                                                                                                                                                                       |
| R&D               | Research and Development: often name of Department within NHS hospitals giving permission to conduct projects on those facilities with patients/staff                                                                                                                                                                                                                                                                               |
| RCT               | Randomised Controlled Trial: A randomised controlled trial (RCT) is a clinical study in which two (or more) forms of care are compared; the participants are allocated to one of the forms of care in the study, in an unbiased way                                                                                                                                                                                                 |
| RDS               | Research Design Service: organisation with a number of experts who can help write the protocol/documents for NIHR grant applications                                                                                                                                                                                                                                                                                                |
| REC               | Research Ethics Committee: authorised by NRES to review study documents for research taking place in the NHS, or social services. Some REC specialise in Clinical Trials, or topics such as research in children, MCA. See NRES website for more detail and other types of research <a href="http://www.nres.npsa.nhs.uk/">http://www.nres.npsa.nhs.uk/</a> All Research in NHS/social services must have been reviewed by a UK REC |
| Research Passport | A system for HEI employed researchers/postgraduate students who need to undertake their research within NHS organisations, which provides evidence of the pre-engagement checks undertaken on that person in line with NHS Employment Check Standards (among them CRB and occupational health checks)                                                                                                                               |
| RfPB              | Research for Patient Benefit: NIHR research funding stream                                                                                                                                                                                                                                                                                                                                                                          |
| RGF               | Research Governance Framework: DH guidance for the conduct of research within the NHS in England (use 2 <sup>nd</sup> edition, 2005)                                                                                                                                                                                                                                                                                                |
| RM&G              | Research Management and Governance                                                                                                                                                                                                                                                                                                                                                                                                  |
| SAE               | Serious Adverse Event                                                                                                                                                                                                                                                                                                                                                                                                               |
| SAR               | Serious Adverse Reaction                                                                                                                                                                                                                                                                                                                                                                                                            |
| SDV               | Source Data Verification: checking the original data record, such as lab reports, patient medical notes against what was transferred onto the CRF/into a database                                                                                                                                                                                                                                                                   |
| Serious-ADR       | Adverse drug reaction which falls in to one of the serious criteria and therefore warrants expedited reporting (serious = resulting in hospitalisation, prolonged hospitalisation, death, life-threatening, congenital anomaly/birth defect or persistent or significant disability/incapacity)                                                                                                                                     |
| SHA               | Strategic Health Authority                                                                                                                                                                                                                                                                                                                                                                                                          |
| SI (i)            | Statutory Instruments: document which defines UK law in on a specific topic, e.g. how to manage a clinical trial                                                                                                                                                                                                                                                                                                                    |
| SI (ii)           | Sub-Investigator (as in ICH-GCP, ICH does not use the term Co-investigator)                                                                                                                                                                                                                                                                                                                                                         |
| Site              | The NHS organisation in which study activities and assessment are performed or the location(s) where trial-related activities are actually conducted. Each site/Trust needs to give R&D approval                                                                                                                                                                                                                                    |
| SLA               | Service Level Agreement                                                                                                                                                                                                                                                                                                                                                                                                             |
| SMO               | Site Management Organisation                                                                                                                                                                                                                                                                                                                                                                                                        |
| SmPC              | Summary of Product Characteristics: smaller version of Investigator Brochure with details on pharmacological effects, side effects, but issued for a product that already holds a marketing licence                                                                                                                                                                                                                                 |
| SOP               | Standard Operating Procedure: detailed written instructions designed to achieve uniformity of the performance of a specific function                                                                                                                                                                                                                                                                                                |
| SRN               | Stroke Research Network                                                                                                                                                                                                                                                                                                                                                                                                             |
| SSA               | Site Specific Assessment: An assessment performed to establish the suitability of a Principal Investigator and a site for the conduct of research; SSA will be performed by the Participating CLRN for each research site (NHS organisation), using an SSI form available in IRAS                                                                                                                                                   |

|                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|--------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Substantial modification | <p>A substantial modification can be defined as an amendment to the protocol or any other study specific documentation, the terms of the REC application or the terms of the CTA application (as applicable) that is likely to affect to a significant degree the:</p> <ul style="list-style-type: none"> <li>The safety or physical or mental integrity of the subjects of the trial;</li> <li>The scientific value of the trial;</li> <li>The conduct or management of the trial; or</li> <li>The quality or safety of any investigational medicinal product used in the trial.</li> </ul> <p>Other changes to the particulars of a study that qualify as substantial modifications include:</p> <ul style="list-style-type: none"> <li>A change of sponsor(s)</li> <li>Appointment of a new Chief Investigator and</li> <li>Extension of the research beyond the planned closing date for recruitment</li> </ul> <p>A substantial modification may not be made to a research study without the favourable opinion from the REC that gave a favourable opinion for the study (the main REC) and as applicable the MHRA. The only exceptions to this rule are:</p> <ul style="list-style-type: none"> <li>The Inclusion of a new research site or</li> <li>The Appointment of a new PI at an individual site</li> </ul> <p>Both of these qualify as substantial modification but as they require further SSA and approval from the REC there is no requirement for notice of modification to the REC. These changes do still however need to be notified to the MHRA (as applicable)</p> |
| SUSAR                    | Suspected Unexpected Serious Adverse Reaction: A Serious Adverse Reaction (SAR) which is Unexpected (i.e. its nature and severity is not consistent with the known information about that product from the Investigator's Brochure or the SmPC) and suspected, as it is not possible to be certain of causal relationship with the IMP                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| TCRN                     | Topic specific Clinical Research Network: includes DRN, DeNDRoN, NCRN, MCRN, MHRN and SRN                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| TMF                      | Trial Master File (file with essential documents held by the Chief Investigator/Sponsor organisation)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| UKCRC                    | United Kingdom Clinical Research Collaboration                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| WHO                      | World Health Organisation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| WMA                      | World Medical Association                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| WT                       | Weight                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

*This Glossary was taken from the NIHR Introduction to Good Clinical Practice (GCP) handbook.*