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

Version 1, 21.10.2025

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

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 contract 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.

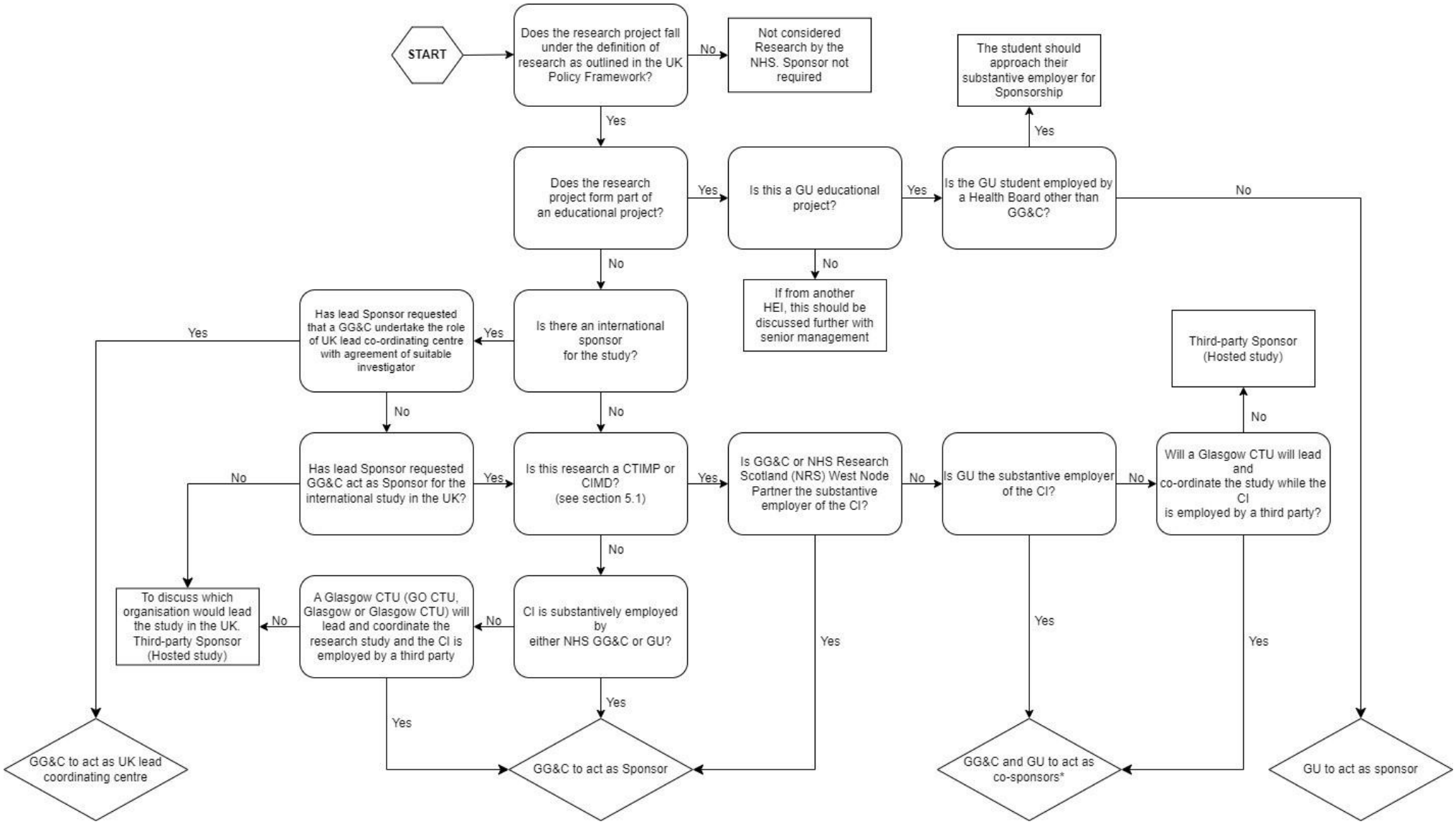
Who may act as sponsor?

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:


START
Does the research project fall under the definition of research as outlined in the UK Policy Framework?
No
Not considered Research by the NHS. Sponsor not required
Yes
Does the research project form part of an educational project?
Yes
Is this a GU educational project?
Yes
Is the GU student employed by a Health Board other than GG&C?
Yes
The student should approach their substantive employer for Sponsorship
No
No
If from another HEI, this should be discussed further with senior management
No
Is there an international sponsor for the study?
Yes
Has lead Sponsor requested that a GG&C undertake the role of UK lead co-ordinating centre with agreement of suitable investigator
Yes
GG&C to act as UK lead coordinating centre
No
Has lead Sponsor requested GG&C act as Sponsor for the international study in the UK?
No
To discuss which organisation would lead the study in the UK. Third-party Sponsor (Hosted study)
Yes
Is this research a CTIMP or CIMD? (see section 5.1)
Yes
Is GG&C or NHS Research Scotland (NRS) West Node Partner the substantive employer of the CI?
No
Is GU the substantive employer of the CI?
No
Will a Glasgow CTU will lead and co-ordinate the study while the CI is employed by a third party?
No
Third-party Sponsor (Hosted study)
No
A Glasgow CTU (GO CTU, Glasgow or Glasgow CTU) will lead and coordinate the research study and the CI is employed by a third party
No
CI is substantively employed by either NHS GG&C or GU?
Yes
Yes
GG&C to act as Sponsor
Yes
GG&C and GU to act as co-sponsors*
Yes
GU to act as sponsor

To request NHSGGC to act as the sponsor for your study, please email the following documents to **ggc.randigrantapplications@nhs.scot**:

- Completed **Strategic Form (**form51-010e_v2-0.docx **– Form 51.10E)**
- **NHSGGC Costing Form (form51-010a_v5-1.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 the CI to suggest 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_v4-0.pdf*

NHSGCCs 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.

please email the following documents to **ggc.randigrantapplications@nhs.scot**:

- Completed **Strategic Form (form51-010e_v2-0.docx)**
- **NHSGGC Costing Form (form51-010a_v5-1.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.

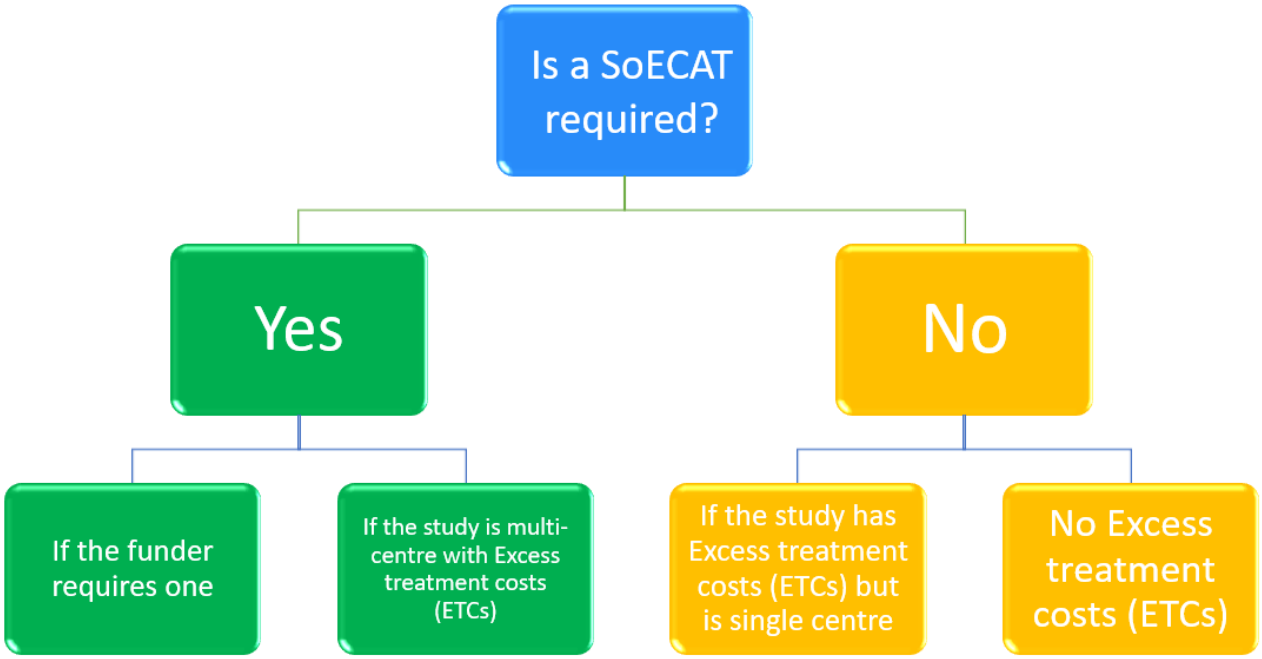
Following submission, a meeting will be arranged with an R&I Coordinator or Facilitator to review the Strategic Form together.

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 site-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.

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 site-based Study Representative is added to review site 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 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:

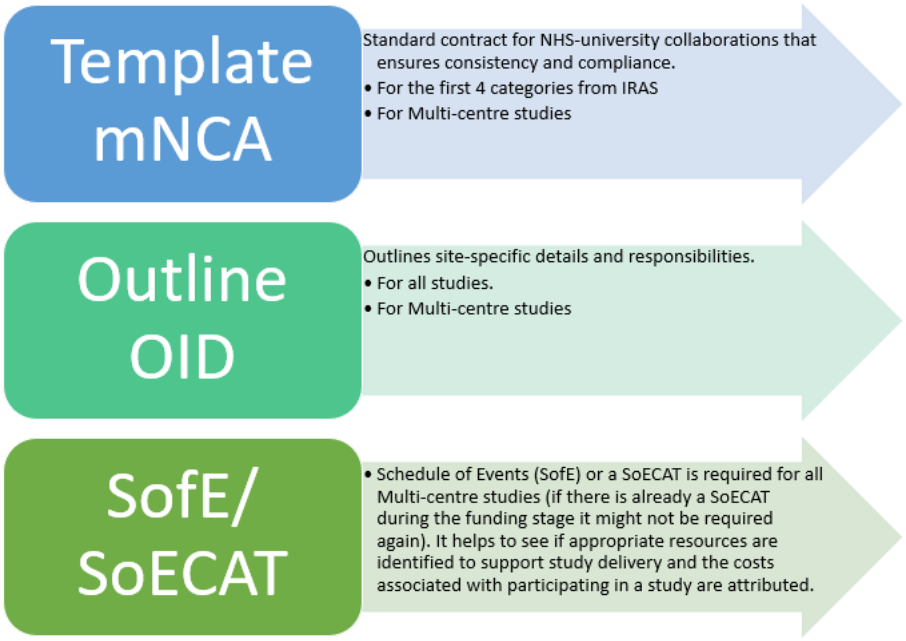
- Purpose of the study
- What participation involves
- Risks and benefits
- Data protection and confidentiality
- Contact details for queries or complaints.
- GDPR transparent wording Transparency wording for all sponsors - Health Research Authority
- Make sure ggc.complaints@nhs.scot email is included.

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. Site 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_NonCommercial_v1-8_April_2024.docx

NHSGCCs SOP on Protocol Development (51.001) - sop51-001_v6-0.pdf
NHSGGCs 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 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_v4-0.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 the Human Tissue act Scotland);
- 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 conformation.

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 (See table below);
- honorary contract /letter of access if NHSGGC is not your substantive employer
- Conformation 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: Localised OID OID appendix email 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 Date valid documents and pre-engagement checks received: 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 the R&I

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

- For any amendments (Substantial or non-substantial)
- 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 site 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**

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 site) 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 Act (Scotland) (HTA)

The Human Tissue (Scotland) Act 2006 governs the removal, retention, and use of human tissue in Scotland, with a strong emphasis on respecting individual wishes through a system of authorisation rather than consent. It applies primarily to tissue from deceased individuals and regulates its use for purposes such as transplantation, research, education, and post-mortem examination. Adults aged 16 and over, and children aged 12 and over, can authorise the use of their tissue, while parental authorisation is required for younger children.

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 sites does not use the HRA/HCRW approval system .

ICH GCP

What is ICH GCP?

Good Clinical Practice (GCP) is the ethical and practical standard to which all clinical research is conducted. The GCP guidelines were developed by the International Conference on Harmonisation (ICH). While these guidelines primarily relate to the conduct of clinical trials of Investigational Medicinal Products (CTIMPs), they are equally relevant and applicable to the conduct of all research.

"Good Clinical Practice is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects." (*Definition from EU Directive 2001/20/EC, article 1, clause 2)*

Compliance with this good practice provides assurance that the rights, safety and well-being of trial subjects are protected, and that the results of the clinical trials are credible and accurate.

Do I need GCP training?
Everyone involved in the conduct of clinical research must have training to ensure they are best prepared to carry out their duties. This is laid down in the Research Governance Framework for Health and Social Care 2005, covering all research in the NHS in Scotland, and in law for those people working on clinical trials.

The principles of GCP state that: Each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective task(s). (*2.8, E6 Guideline for Good Clinical Practice*)

It is highly recommended by NHS Greater Glasgow & Clyde NHS that GCP training should be completed every 2 years.

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_v4-0.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

NHSGGC SOP on Research Passports (52.005) - sop52-005_v5-0.pdf

Amendments

What are amendments?

Amendments are changes made to your study after a REC favourable opinion has been granted. These amendments can be substantial or non-substantial.

For all studies, it is the responsibility of the Sponsor (NHSGGC) to determine whether an amendment 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 or non-substantial amendment

What are substantial amendments?

Substantial amendments are defined as amendments to the original REC application or to the protocol or any other supporting documentation that is likely to affect to a significant degree:

- the safety or physical or mental integrity of participants
- the scientific value of the research
- the conduct or management of the research
- the quality or safety of any investigational medicinal product used

Examples of substantial amendments:

- changes to the design or methodology of the study, or to background information likely to have a significant impact on its scientific value;
- changes to the procedures undertaken by participants;
- changes likely to have a significant impact on the safety or physical or mental integrity of participants, or to the risk/benefit assessment for the study;
- significant changes to study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation, letters to GPs or other clinicians, information sheets for relatives or carers;
- a change of sponsor(s) or sponsor's legal representative;
- appointment of a new chief investigator
- a change to the insurance or indemnity arrangements for the study;
- a CTIMP or regulated investigation of a medical device wishing to add a new Non-NHS/HSC site
- appointment of a new principal investigator at a non-NHS/HSC trial site in a CTIMP or regulated investigation of a medical device
- temporary halt of a study to protect participants from harm, and the planned restart of a study following a temporary halt;
- a change to the definition of the end of the study;
- any other significant change to the protocol or the terms of the REC application.

Examples of non-substantial amendments:

- minor changes to the protocol or other study documentation, e.g. correcting errors, updating contact points, minor clarifications;
- updates of the investigator's brochure (unless there is a change to the risk/benefit assessment for the trial);
- changes to the chief investigator's research team
- changes to the research team at particular trial sites (other than appointment of a new principal investigator at a Non-NHS/HSC site in a CTIMP or a regulated investigation of a medical device);
- changes in funding arrangements;
- changes in the documentation used by the research team for recording study data;
- changes in the logistical arrangements for storing or transporting samples;
- inclusion of new sites and investigators (other than a CTIMP or a regulated investigation of a medical device wishing to add a new Non-NHS/HSC site)
- change to the study end date.

Preparing amendments

To initiate an amendment, please complete the amendment tool, referring to the 'Glossary of Amendment 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, amendments 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 amendment tool, a Sponsor amendment decision email will be sent allowing you to submit your amendment to IRAS.

Submitting amendments

Amendments 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 amendment account to proceed.

- Click create new amendment
- 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 amendment 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 amendment is automatically sent to revelent approving bodies. You will get an automatic reply (keep this response as you will need to inform sites if your study is multicenter)

For more information and help on submitting an amendment using the following link: https://www.myresearchproject.org.uk/help/hlpamendments.aspx

Local R&I Amendment Approval

Once the amendment has been submitted you need to notify all sites of the amendment.

Notifying sites

- Single Centre Studies
  - In Scotland, single centre study amendments shall be sent directly to R&I office and research team at the participating organisation as per the information in the Amendment Tool
- Multicentre Studies
  - For multicentre studies, amendments should be sent to gram.nrspcc@nhs.scot for Scottish sites. For English and Welsh sites, 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 amendment, they will review it and issue local R&I approval for Category A and applicable Category B amendments. Category B amendments refer to changes in a research project that impact only specific participating NHS/HSC organisations, rather than all sites involved in the study. For Category C amendments, 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 amendment 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 Amendment review & Approval - sop51-021_v5-0.pdf

Safety Reporting

To be compliant with Good Clinical Practice (GCP), Research Governance Framework (RGF), Medical Devices Regulations 2002, Chief/Principal Investigators of Non-CTIMP clinical studies have a responsibility to record and report SAEs.

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/amendments, 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.

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. Sites 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 sites 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 non-substantial amendment.

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 sites 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&D via our generic GRANTs email address- 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-center study, you are responsible to contact sites and follow the Project Manager 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/

NHSGGC contacting wider R&I team 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 Amendments 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

Human Tissue Authority Scotland (HTA) Human Tissue (Authorisation) (Scotland) Act 2019

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/

Public Benefit and Privacy Panel (PBPP)
www.informationgovernance.scot.nhs.uk/pbpphsc/home/for-applicants/

Confidentiality Advisory Group (CAG) (English sites)
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

Appendix A – Defining Research

RESEARCH	SERVICE EVALUATION	CLINICAL/ NON-FINANCIAL AUDIT	USUAL PRACTICE (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 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. 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?" 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. 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. However, some quantitative research such as descriptive surveys, do not involve interventions. Qualitative research – seeks to understand better the perceptions and reasoning of people.	Involves an intervention in use only. 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. 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. 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. 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 http://hra-decisiontools.org.uk/ethics/ for more information.	Does not require REC review.	Does not require REC review.	Does not require REC review.

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
Amendment	A written description of a change or formal clarification. Substantial amendments (See below under 'Substantial Amendment') to protocol, participant information/consent require REC, R&D, MHRA approval, Non-substantial amendments should be 'notified' to REC, R&D, MHRA
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	Complains 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 www.healthtalkonline.org
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 Act or Human Tissue Authority
HTA	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) http://www.mhra.gov.uk/home/groups/l-unit1/documents/websiteresources/con009394.pdf
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 www.isrctn.org or www.controlledtrials.com/mrct
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 amendments	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 amendments).

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 http://www.nres.npsa.nhs.uk/ 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 2nd 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 Amendment	A substantial amendment 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: The safety or physical or mental integrity of the subjects of the trial; The scientific value of the trial; The conduct or management of the trial; or The quality or safety of any investigational medicinal product used in the trial. Other changes to the particulars of a study that qualify as substantial amendments include: A change of sponsor(s) Appointment of a new Chief Investigator and Extension of the research beyond the planned closing date for recruitment A substantial amendment 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: The Inclusion of a new research site or The Appointment of a new PI at an individual site Both of these qualify as substantial amendments but as they require further SSA and approval from the REC there is no requirement for notice of amendment to the REC. These changes do still however need to be notified to the MHRA (as applicable)
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.