SOP number	**51.017**	Version	**5.0**
Title	**Registration of Research Studies on Public Databases**		

Prepared by	Louise Ner
Approved by	Melissa Robert
Released by	Jesse Dawson

SOP category	NHS GG&C Sponsor R&I

Staff category

Staff Category	R	A	C	I
R&I Systems & Operations Manager		X		
Project Managers	X			
Senior Research Administrators	X			
Research Information Officer	X			
Chief Investigator and relevant designees	X			
Innovation Project Managers	X			
Sponsor Research Co-ordinators			X	
Sponsor Innovation Co-ordinator			X	
University of Glasgow Research Regulation and Compliance Team				X

1. Scope

This procedure applies to all research studies sponsored by NHS Greater Glasgow & Clyde (NHSGGC), or co-sponsored with the University of Glasgow (UoG), where registration on a publicly accessible database is required by legislation, Research Ethics Committee (REC) conditions or applicable policy.

2. Purpose

This SOP describes the process of registering applicable NHSGGC-sponsored and co-sponsored research studies on publicly accessible databases, in accordance with UK clinical trials legislation, HRA (Health Research Authority) requirements and principles of research transparency.

3. Procedures

3.1. Background

Registration of research trials on publicly accessible databases is a condition of a favourable REC opinion for certain categories of research and, for regulated trials, a legal requirement under the Medicines for Human Use (Clinical Trials) Regulations as amended. It is a condition of a favourable ethics opinion that all research tissue banks are registered on the UK Clinical Research Collaboration (UKCRC) Tissue Directory: UKCRC Tissue Directory - Register a new Sample Resource

Public registration and timely reporting of results support compliance with UK clinical trials legislation, transparency obligations, and prevention of selective reporting. NHSGGC as Sponsor, retains overall responsibility for ensuring these requirements are met, even where tasks are delegated.

For the purposes of this SOP, the requirement for registration is informed by definitions and guidance published by UK regulatory bodies, including the MHRA and HRA, and aligned with the World Health Organisation (WHO) trial registration framework.

3.2. Research Studies that Require Registration

The following categories of research studies normally require registration on a publicly accessible database:

- Clinical Trials of Investigational Medicinal Products (CTIMPs)
- Clinical Investigations of Medical Devices (CIMDs)
- Combined trial of an investigational medicinal product and an investigational medical device.
- Other clinical trials to study a novel intervention, or randomised clinical trials to compare interventions in clinical practice
- Research tissue banks (see section 3.6)

3.3. Research Studies that do not Require Registration

The following generally do not require registration unless specified by the REC or funder:

- Basic science studies involving procedures with human participants
- Studies administering questionnaires/interviews for qualitative analysis, or using mixed qualitative/quantitative methodology
- Studies involving qualitative methods only
- Studies limited to working with human tissue samples and/or data only
  Research databases
  Other studies that do not meet the definition of a registrable research study

3.4. Registration Timing Requirements

All studies that require to be registered on a publicly accessible database must be registered before recruitment of the first participant, unless a justified deferral has been approved through IRAS.

For clinical trials regulated under the Medicines for Human Use (Clinical Trials) Regulations, registration must additionally occur no later than 90 calendar days after the trial has received the required regulatory and ethics approvals, where this deadline falls earlier.

3.5. Process of Research Project Registration

The Chief Investigator (CI), or an appropriately delegated individual, is responsible for completing and maintaining accurate registration records on the relevant public database. NHSGGC, as Sponsor, retains oversight responsibility and may perform checks to confirm ongoing compliance.

Registration must be completed using an established publicly accessible registry recognised by UK regulatory bodies, such as ISRCTN or ClinicalTrials.gov. Where registration is a condition of funding e.g. studies funded by NIHR or CSO, the registry specified in the award documentation must be used. This should be appropriately costed for at grant stage (see SOP 51.010).

Eligible studies that are funded and/or adopted onto the NIHR or NRS research portfolio must also be registered on the Central Portfolio Management System (CPMS), in line with SOP 52.010. Registration on CPMS is undertaken by the Research Information Officer within the R&I Systems Team.

3.6. Registration of Trials Submitted through Combined Review

For clinical trials submitted via Combined Review, HRA may arrange registration of the trial with ISRCTN on behalf of the Sponsor using information submitted through IRAS. Where the CI intends to register the trial on an alternative recognised registry (e.g. ClinicalTrials.gov), this must be declared in IRAS at the time of application. Once available, the registry identifier must be provided to the REC and HRA in line with IRAS guidance.

Registration on ClinicalTrials.gov should be done once the appropriate level of information is available to enter on the database, for example, all study documents have been approved by the Sponsor Research Co-ordinator (SRC), Sponsor Innovation Co-ordinator (SIC) or Sponsor Research Facilitator (SRF) and are ready for submission to the appropriate review bodies (see SOP 51.014). The Senior Research Administrator (SRA) will provide the CI (or designee) with the NHSGGC ClinicalTrials.gov account details and instructions (WI 51.016A).

3.7. Data to be Entered in Registry

Data entered into public registries must align with the WHO Trial Registration Data Set and must be consistent with information submitted and approved via IRAS, including the protocol and associated study documentation.

Registered records must be kept accurate and up to date throughout the lifecycle of the study by CI or delegate, including recruitment status, completion status and results reporting, in line with HRA and MHRA expectations.

3.8. Legacy EU-registered trials

For UK trials registered in the EU Register prior to 31 December 2020, results should be published in the registry where the study is registered. MHRA should be notified once results are posted. Summary results can continue to be posted by the CI (or designee) via EudraCT, however, MHRA cannot update the status of the trial to ‘completed’ within the EU register. Where end-of-trial notifications have been received but results reporting remains outstanding, the MHRA may undertake follow-up with the Sponsor.

3.9. Research project with non-UK lead Sponsors

Where NHSGGC acts as Sponsor or Co-Sponsor for a study led by a non-UK Sponsor, the CI must confirm whether the study has already been registered. Where registration is delegated to NHSGGC, an English-language public registry must be used in line with this SOP.

3.10. Registration of Research Tissue Banks

Registration of research tissue banks must occur within six weeks of favourable ethics opinion or six weeks first holding tissue for research purposes, whichever is sooner. Registration records must be kept accurate and up to date, and the UKCRC Tissue Directory registration reference number must be recorded within the relevant IRAS dataset. Registration information may be reviewed by the HRA as part of ongoing oversight, assurance activities, or ethics approval renewal processes where applicable. More information about registration of research tissue banks can be accessed here: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-tissue-banks-and-research-databases/

4. Referenced documents

- SOP 51.010: Preparation and Review of Grant Applications and Costs
- SOP 51.014: Preparation and Initial Submission of Research Studies to the Research Ethics and Regulatory authorities IRAS/Combined Review Forms for Sponsored & Co-sponsored Studies
- SOP 50.024: Management of the Central Portfolio Management System
- WI 51.017A: Guidance on ClinicalTrials.gov NHSGGC login details and template email
- Medicines for Human Use (Clinical Trials) Regulations 2004, as amended
- MHRA & HRA Guidance on Research Transparency (latest version)
- International Committee of Medical Journal Editors, Editorial, 2004
- World Health Organisation, http://www.who.int/ictrp/en/
- ISRCTN Registry
- https://www.clinicaltrials.gov/
- https://www.who.int/clinical-trials-registry-platform/network/who-data-set
- Research registration and research project identifiers - Health Research Authority (hra.nhs.uk)
- https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-tissue-banks-and-research-databases/

5. Related documents

- SOP 51.007: Identifying a Sponsor Organisation
- NRS Funding Guidance: Annex 3

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	05/02/2013	Release of first version	No
2.0	08/03/2018	Updated to reflect HRA criteria for registration. Updated to template v1.4.	No
3.0	17/12/2018	Responsibility for database registration and compliance has moved from the coordinator, to the CI.	No
4.0	26/07/2023	Updated as per latest MHRA guidance on Clinical trials reporting requirements on: - Registration of trials submitted through combined review (post January 2022) - MHRA Requirements for UK trial registered in the EU Register prior to 31 December 2020 - Registration of research tissue banks Updated the links used as resources	No
5.0	14/05/2026	Updated to align with MHRA clinical trials regulatory reforms effective 28 April 2026, including clarified registration timelines, strengthened Sponsor oversight, and improved differentiation between CTIMP and non-CTIMP requirements.	No