SOP number	**51.017**	Version	**4.0**
Title	**Registration of research projects on public databases**		

Prepared by Signature	Pamela Sandu Date
Approved by Signature	Melissa Robert Date
Released by Signature	Julie Brittenden Date

SOP category	NHS GG&C Sponsor R&I

Staff category

Staff Category	R	A	C	I
R&I Systems Manager		X		
Project Managers	X			
Senior Research Administrators	X			
Research Information Officer	X			
Chief Investigator and relevant designees	X			
Sponsor Research Co-Ordinators			X	
R&I Innovation Contracts Manager/Coordinator			X	
University of Glasgow Head of Research Regulation and Compliance and Research				X

1. Scope

This procedure applies to research studies and clinical trials Sponsored by NHS Greater Glasgow Health Board (NHSGGC), or co-sponsored with University of Glasgow (UoG).).

2. Purpose

This SOP will describe the process of registering research projects Sponsored by NHSGGC or Co-Sponsored with The University of Glasgow (GU) on publicly accessible databases.

3. Procedures

3.1. Background

It is a condition of a Research Ethics Committee (REC) favourable opinion that a clinical trial matching one of the descriptions in 3.1.1 is registered in a publicly accessible database, ideally before the first participant is recruited and no later than six weeks after this date, unless there is a valid reason not to. The most common valid reasons are that registration would divulge sensitive (e.g. work with animal products or human foetal material) or proprietary information. In this instance the CI (or designee) should submit a request to defer registration of clinical trial on a publicly accessible database by answering the deferral question set in the Integrated Research Application System (IRAS) application.
Deferrals are valid for 12 months, however the deferral period can be extended by 12 months at a time until the study comes to an end. Registration is intended to prevent selective reporting by Sponsors, particularly relating to research projects where the result was negative. Transparency of research projects provides information to other researchers, clinicians and patients, thus ensuring that all available evidence is used to inform decisions on healthcare including future research (International Committee of Medical Journal Editors, 2004).

The definition of a research project that requires to be registered on a public database is taken from the World Health Organisation.

"A research study that prospectively assigns human participants to one or more health-related interventions or comparison groups to evaluate the effects on health outcomes. Health-related interventions include any intervention used to modify a biomedical or health related outcome (e.g. drugs, surgical procedures, radiological procedures devices, behavioural treatments, dietary interventions and process of care changes). Health outcomes include any biomedical or health-related measures obtained in participants".

For the purposes of this SOP, research study in the above definition refers to research project.

3.1.1. Research projects that require registration:

- 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 (detailed at section 3.6)

3.1.2. Research projects that do not require registration:

- 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 any of the descriptions given in 3.1.1 or 3.1.2

3.2. Process of Research Project Registration

As per MHRA and HRA published guidance, the CI (or a designee) should use existing and established international registers such as the ISRCTN registry, or ClinicalTrials.gov, to ensure the public is aware of their trial. It is the responsibility of the CI (or a designee) to enter the data onto the applicable database and maintain through the trials life. In the scenario where a research project has received funding from an external organisation, the funder may state a preferred public database; this information should be detailed in the funding organisation award guidance.

Studies coordinated by the Cancer Research UK Glasgow Clinical Trials Unit (CRUK CTU) will follow this SOP and the CRUK CTU SOP CTU_TCC_GEN_020_Public_Databases.

All research projects detailed in section 3.1.1 and 3.1.2 that are eligibly funded and/or confirmed to be adopted onto the National Institute for Health Research (NIHR) portfolio (as per NRS Funding Guidance: Annex 3), should be registered on a further public database -The Central Portfolio Management System (CPMS). CPMS is a cloud-based system that holds the NIHR Clinical Research Network (CRN) Portfolio, as well as the network portfolios of Northern Ireland, Scotland and Wales. Projects registration on CPMS is performed by the research Information Officer (part of R&I Systems Team) as per SOP 52.010.

3.3. Registration of trials submitted through combined review

HRA has partnered with ISRCTN Registry to register trials submitted through combined review on behalf of sponsors.

All clinical trials of investigational medicinal products (CTIMPs) and combined trials of an investigational medicinal product and an investigational medical device (IMP/device trials) submitted on or after 1 January 2022 for combined review in the new part of IRAS will have study information sent directly to ISRCTN for registration.

If a trial approved through combined review is registered, or will be registered, on ClinicalTrials.gov, the CI (or designee) can request that it is not automatically sent for registration with ISRCTN. The intention to register on ClinicalTrials.gov needs to be clearly stated by answering the deferral question in the IRAS application. If the ClinicalTrials.gov registration number is not included in the IRAS application, this should be emailed to the REC and HRA (deferrals@hra.nhs.uk), as soon as it is available.

The study will be published on the HRA research summaries webpage. Furthermore the trial final report will include a lay summary of results published alongside the rest of the research summary on HRA website.

The 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 Research Co-ordinator as Sponsor's representative and are ready for submission to the appropriate review bodies REC, R&I and MHRA (if applicable). The Senior Research Administrator (SRA) will provide the CI (or designee) with the NHSGGC ClinicalTrials.gov account details and instructions (WI 51.016A).

3.4. Data to be entered

The data to be entered on publicly accessible databases is based on the WHO Trial Registration Data Set: WHO data set.

Information to populate the fields in public databases can be retrieved from the IRAS REC and R&I submission forms as well as the protocol. Sponsor should always be selected as NHSGGC for sole-sponsored studies. If the study is Co-Sponsored, GU should be entered as a collaborator or a Co-Sponsor.

Details of registered research projects should be updated once they have started, throughout the period of active recruitment and at the end of the project. CIs, or designee, that have registered research projects will receive update requests from the public databases, it is the responsibility of the CI, or designee, to ensure updates are entered on the research project.

For UK trials registered in the EU Register prior to 31 December 2020:

- Results should be published in the public register where the study is registered and the MHRA informed when this is done.
- 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').
- MHRA have updated their IT system to run a report for end of trial notifications received and follow-up with the trial sponsor where a case has not been closed (i.e. results reported).

3.5. Research project with non-UK lead Sponsors

In the scenario that the research project is led by a non-UK Sponsor and NHSGGC have been requested to act as Sponsor or Co-Sponsor in a specified territory(ies), the CIs should ascertain if the Global Sponsor has already registered the project. If it has not been registered in an English language database and the Global Sponsor has delegated the responsibility of registration to the local Sponsor/Co-Sponsor, the process in section 3.2 should be followed.

3.6. Registration of research tissue banks

It is a condition of favourable ethics opinion that all research tissue banks are registered on the UK Clinical Research Collaboration UKCRC Tissue Directory - Register a new Sample Resource (biobankinguk.org). The research tissue bank should be registered no later than six weeks after favourable opinion, or six weeks after the research tissue bank holds tissue with the intention to provide for research purposes.

Registration means having added details of the types of tissue samples held in the tissue bank. HRA monitors registration details as part of annual progress reporting and the research registration reference number should be entered in the dataset on IRAS.
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 52.010 - Registration on the Central Portfolio Management System
- WI 52.017A - Guidance on ClinicalTrials.gov NHSGGC login details and template email
- NRS Funding Guidance: Annex 3
- 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
- SOP 51.041: Preparation and submission of IRAS forms

6. Document history

Version	Date	Description
1.0	05/02/2013	Release of first version
2.0	08/03/2018	Updated to reflect HRA criteria for registration. Updated to template v1.4.
3.0	17/12/2018	Responsibility for database registration and compliance has moved from the coordinator, to the CI.
4.0	26/7/2023	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