Transparency: Registering and reporting research studies on a publicly accessible database

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Author:	Jo-Anne Robertson
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1 Introduction

1.1 The Academic & Clinical Central Office for Research & Development (ACCORD) is a joint office comprising clinical research management staff from NHS Lothian (NHSL) and the University of Edinburgh (UoE).

1.2 All health and social care research studies should be registered on a publicly accessible register.

1.3 It is important to register all health and care research studies to ensure all research is carried out in a transparent and open way, allowing the facilitation of ethical research practice. This will improve research integrity and reduce research waste.

1.4 Registering a study can improve recruitment to studies, allows researchers to build on previous findings and helps both professionals involved in healthcare and the public to make informed choices.

1.5 Once a study is registered it is of the upmost importance that the record is regularly updated throughout the lifecycle of the study.

1.6 NHSL and the UoE assume the role of Sponsor and fully support the commitment to transparency in research, and expects all staff, students and researchers to uphold the highest standards. Promoting transparency enhances public trust in the research process.

2 Scope

2.1 This policy is applicable to researchers working within NHSL and/or UoE, planning and conducting health and social care research.

2.2 This policy is also applicable to ACCORD personnel who review research studies e.g. Sponsor Representatives.

3 Policy

3.1 Registering a clinical trial for studies using the Integrated Research Application System (IRAS)

3.1.1 Clinical trials are defined as:

- A clinical trial of an investigational medicinal product (CTIMP).
- A clinical investigation or other study of a medical device.
- A combined trial of an investigational medicinal product and an investigational medical device.
- Any other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

3.1.2 The Declaration of Helsinki states that all clinical trials must be registered on a publicly accessible database.

3.1.3 Registering a clinical trial is a condition of the favourable opinion issued by the research ethics committee (REC).

3.1.4 A clinical trial should be registered before the first participant is recruited, and no later than 6 weeks after. Failure to register within these timelines is a breach of the REC favourable opinion, unless a deferral has been lodged. This option can be utilised if there are any commercial sensitivities associated with the study.

3.1.5 Studies can apply for a deferral, for example if there are commercial sensitivities, via the HRA. Phase 1 CTIMP studies only involving healthy volunteers will automatically be given a deferral for transparency requirements for up to 30 months after the end of the trial.

3.1.6 If a clinical trial is terminated before any trial procedures set out in the protocol have been initiated (for example, patient screening or consent), the trial does not need to be registered.

3.1.7 The Health Research Authority (HRA) perform annual audits to ensure that all clinical trials they have given an ethical approval to have been registered in a timely manner. The results of the audit are published and highlight any study that has not been registered and the institute responsible.

3.1.8 The UoE Research Governance Manager, or designee, will periodically ensure that all clinical trials are registered and will contact CI/study teams if this requirement has not been fulfilled.

3.1.9 Studies should only be registered on one database.

3.1.10 Not registering and maintaining a clinical trial registration record could affect future Sponsorship applications.

3.1.11 All CTIMPs and combined trials (IMP/device trials) submitted for combined review on the Integrated Research Application System (IRAS) will automatically have study information sent directly to ISRCTN for registration. No other action is required to register a study of this nature. ISRCTN may contact the researcher for some additional information to finalise the registration. If a trial is registered with clinitrials.gov, researchers can request that the study is not registered with ISRCTN.

3.1.12 The following types of clinical trial are not automatically registered:

- a clinical investigation or other study of a medical device, or
- any other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice), and
- clinical trials conducted in a Global Health setting.

Investigators are required to register these clinical trials on a suitable registry. The HRA states that a suitable registry would either be ClinicalTrials.gov or ISRCTN (as per WHO International Clinical Trials Registry Platform).

3.2 Registering all other studies

3.2.1 Although not a condition of a favourable opinion from a research ethics committee, it is considered good practice to register all health and social care research for the reasons outlined in the Section 1 Introduction.

3.2.2 Clinicaltrials.gov and ISRCTN databases can be used however they may not be the most suitable register depending on the study type. Therefore, every effort should be

made to locate a suitable registry.

3.2.3 Non-commercial studies included on the NIHR CRN Portfolio can qualify for free ISRCTN registration from the Department of Health and Social Care (DHSC).

3.3 Requesting access to registers

3.3.1 To gain permission to clintrials.gov the study team should contact resgov@accord.scot and a member of the Research Governance team will add user permissions. The Study team should send the name and email address of the person responsible for the maintenance of the study record along with the Sponsor number (ACXXXXXX) if known, in order to set up permissions.

3.3.2 For ISRCTN, study teams can register directly via https://www.isrctn.com/.

3.3.3 Permission for registration access can only be sought for studies Sponsored by UoE and or NHSL only.

3.4 Maintaining registration records

3.4.1 All studies that are registered on a database must be checked regularly and updated where required by the study team.

3.4.2 As a minimum, records should be checked annually and be updated when an amendment is submitted which affects the information contained in the registration record (e.g. when a study is extended).

3.4.3 Periodically, Clintrials.gov sends a reminder to all record owners. Clintrials.gov can impose fines if records are not kept updated under certain conditions.

3.4.4 ISRCTN send reminders to investigators to update records at certain points in a study's lifecycle to ensure that they are as up-to-date and accurate as possible). ISRCTN also send a reminder to the Sponsor if the registry record has not had either a results publication or a basic results summary added within 12 months of the overall end date.

3.4.5 For all other registries, reminders may be sent to record owners. It is the responsibility of the researcher to check requirements to ensure compliance.

3.4.6 If the study record owner changes during the study, this should be reflected on the registration database.

3.5 Points to consider for registration of all studies

3.5.1 Consider where a study will be registered at an early stage and include any applicable costs within the funding application. This includes ensuring that results are reported up to a year post study completion. Details of the public register including registration number should be detailed on the study protocol.

3.5.2 Ensure study information is kept up to date on the registry.

3.5.3 Researchers should ensure that they are aware of any funder stipulations for study registration.

3.6 Reporting Results on a Publicly Accessible Database

3.6.1 Results should be made available in the public register where the study was initially registered within 12 months of the end of study. Further details on this requirement is detailed in CR011 (Research Study Reports and Publication of Results).

3.6.2 As well as uploading to the public register, participants in the research study should be informed of the findings. Consideration should be given to how the results will be communicated (e.g., newsletter, website), when the findings will be made available and whether participants want to be informed of the findings. More advice is available via the HRA website.

4 References and Related Documents

- https://www.isrctn.com/
- Home | ClinicalTrials.gov
- Trial registration (who.int)
- Declaration of Helsinki – WMA – The World Medical Association
- Research registration and research project identifiers - Health Research Authority (hra.nhs.uk)
- RDN Portfolio | NIHR

5 Document History

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1.0	16 JUN 2025	New Policy

6 Approvals

Sign	Date
Jo-Anne Robertson (28-May-2025 11:11 GMT+1) AUTHOR: Jo-Anne Robertson, Research Governance Manager, UoE, ACCORD	28-May-2025
Marise Bucukoglu (28-May-2025 11:12 GMT+1) APPROVED: Marise Bucukoglu, Head of Research Governance, UoE, ACCORD	28-May-2025
Gavin Robertson (28-May-2025 11:11 GMT+1) AUTHORISED: Gavin Robertson, QA Coordinator, NHSL, ACCORD	28-May-2025

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