UNIVERSITY OF WARWICK

STANDARD OPERATING PROCEDURE 28

Transparency in Clinical Research Studies

(Registering studies, dissemination of results and data sharing)

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Version 5.0	15 May 2026	Biennial review: New template, minor amends to text in line with the amended UK Clinical Trial Regulations (2025), update of CRN to RDN, 'How to register' paragraphs replaced with flowchart.
Version 4.0	08 Nov 2023	Biennial review: Updates to trial registration requirements.
Version 3.0	24 Aug 2021	Biennial review: Change to new format. Web links updated, minor amends to text.
Version 2.0	25 July 2019	Change of title, addition of information on ensuring research transparency throughout research study.
Version 1.5	8 January 2019	Biennial review: Change to new format. Minor amends to text. Web links updated. Addition of requirement to keep registration data up to date.
Version 1.4	4 Dec 2015	Web links updated. Changes to instructions for using the ISRCTN website.
Version 1.3	25 Nov 2013	Addition of HRA requirement to register all trials as a condition of favourable ethical opinion.
Version 1.2	23 April 2012	Website links updated. Trial detail requirements for registration updated.
Version 1.1	21 April 2010	Addition of information on free ISRCTN registration for eligible NIHR CRN Portfolio trials.
Version 1.1	31 Jan 2008	Biennial review: Format change.
Version 1.0	March 2006	

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CONTENTS

1 Purpose and Scope

To describe the requirement for ensuring transparency in clinical research and is applicable to all University of Warwick staff working on clinical research studies. This SOP covers the requirements under the amended UK clinical trial regulations that came into force 28 April 2026. CTIMPs that started before this date should follow the transitional arrangements outlined by the MHRA. The HRA have updated guidance for non-CTIMPs to bring these in line with the new legal requirements for CTIMPs.

2 Acronyms

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTIS	The EU Clinical Trials Information System
EMA	European Medicines Agency
HRA	Health Research Authority
ICMJE	International Committee of Medical Journal Editors
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
ISRCTN	International Standard Registered Clinical/soCial sTudy Number
MHRA	Medicines and Healthcare products Regulatory Agency
NIHR	National Institute for Health and Care Research
QA	Quality Assurance
R&IS	Research & Impact Services
RCT	Randomised Controlled Trial
RDN	Research Delivery Network
REC	Research Ethics Committee
SOP	Standard Operating Procedure
TMF	Trial Master File
WCTU	Warwick Clinical Trials Unit
WHO	World Health Organisation

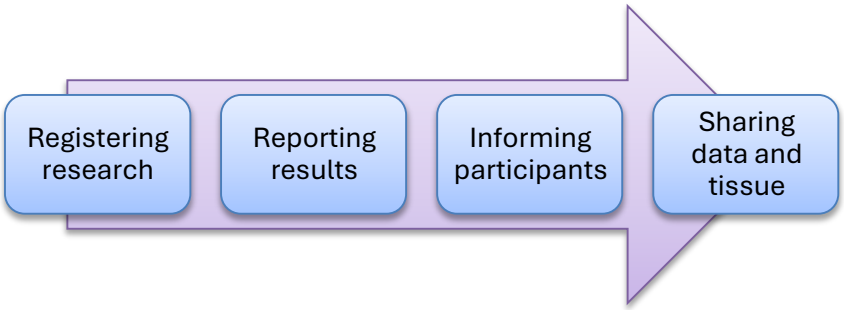
3 Definitions

Research Transparency	Ensuring that clinical trials are prospectively registered in a publicly accessible registry, that summary and lay results are published within required timelines, that findings are reported in full, irrespective of study outcome and data are made available responsibly for subsequent analyses.

4 Background

Research transparency is central to ethical research practice. Research studies should be registered, and the results made public, so that participants are protected from unnecessary research, and patients benefit from improved outcomes and care informed by high quality studies.

Research transparency has four key elements:



When applying for approval for a study, it is expected that researchers have a plan for meeting ethical standards in research transparency. RECs will only give a favourable opinion on the condition that the study is registered on a public database.

When research is carried out openly and transparently, the benefits include:

- Patients and the public can see what research is taking place and access clear information about the results.
- Patients, service users and carers know about research that is relevant to them, giving them the opportunity to join studies.
- Health professionals, commissioners, researchers, policy makers and funders can use research findings to make informed decisions.

All studies designed to assess the efficacy of healthcare interventions (both observational and interventional) are eligible to be registered with the ISRCTN scheme.

Registration on a publicly accessible database is not a legal requirement for Non-CTIMPs, but it is an ethical expectation under the UK Policy Framework for Health and Social Care Research. In addition, prospective registration is required for written articles to be eligible for publication in journals belonging to the ICMJE, and the NIHR requires all NIHR-funded studies to be registered on a publicly accessible database.

The ICMJE does not advocate one particular registry, but its member journals will require authors to record their study in a registry that meets several criteria. For further details on publication requirements, refer to SOP 22 'Publication and Dissemination'.

For publication the registry of the study must be accessible to the public at no charge. It must be open to all prospective registrants and managed by a not-for-profit organisation. There must be a mechanism to ensure the validity of the registration data, and the registry should be electronically searchable.

Use of the ISRCTN register fulfils all the criteria for the ICJME.

Other acceptable registries for ICMJE are listed here: https://www.icmje.org/about-icmje/faqs/clinical-trials-registration/.

Clinical research may be registered on http://www.clinicaltrials.gov, a publicly accessible international registry of clinical studies. Studies recruiting participants outside the UK may be subject to additional country-specific registration requirements, which must be identified and met as applicable.

For other types of research, not limited to: observational, feasibility or epidemiological studies, registration is also encouraged wherever possible. It may be possible to register a study through an NHS

organisation, or a medical research charity register, or publish the study protocol through an open access publisher.

In general, registration is not expected for projects undertaken entirely for educational purposes below doctoral level.

5 Responsibilities

Chief Investigator (or delegate)	• Register study on a publicly accessible registry before recruitment begins • Ensure the register is kept up to date throughout the study • Publication of results within the required regulatory timelines • Ensure results are made available and/or communicated to participants (or their representatives) appropriately • Include clear plans for future data sharing in the protocol and supporting documents
Sponsor	• Ensure appropriate arrangements are in place to meet transparency requirements • Oversee that the CI and study team fulfil these responsibilities and that governance processes support compliance

6 When

The UK HRA expects registration of all clinical trials **before the first participant is recruited or within 90 calendar days of receiving MHRA clinical trial authorisation and a Research Ethics Committee (REC) favourable opinion, whichever is sooner**. This is in line with researcher and sponsor duties as set out by the World Health Organisation (WHO), current Declaration of Helsinki, the amended UK clinical trial regulations and UK Policy Framework for Health and Social Care.

Failure to register the study within **six weeks** of the recruitment of the first UK participant is a breach of the favourable ethical opinion, unless a request to defer registration has been granted by the HRA and is still valid.

If a study is already registered when applying for ethical and regulatory approvals, the registration number should be included. If registration occurs after submitting the application, email the REC with your registration number as soon as possible.

The ICJME states that they will only consider a study for publication if it was registered before the enrolment of the first participant. Failure to do so may prevent publication in key journals.

The mandatory ethical and legal requirement to register applies to clinical trials which fit the definition of at least one of the following categories:

- CTIMP
- Clinical investigation or other study of a medical device
- Combined trial of an IMP or investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

7 How

7.1 Study Registration

7.1.1 CTIMPs

The HRA will automatically register CTIMPs with UK-only sites, that are submitted through the combined review process, with the ISRCTN Registry. Transparency is regularly monitored by the HRA, so registry updates and results reporting are actively checked.

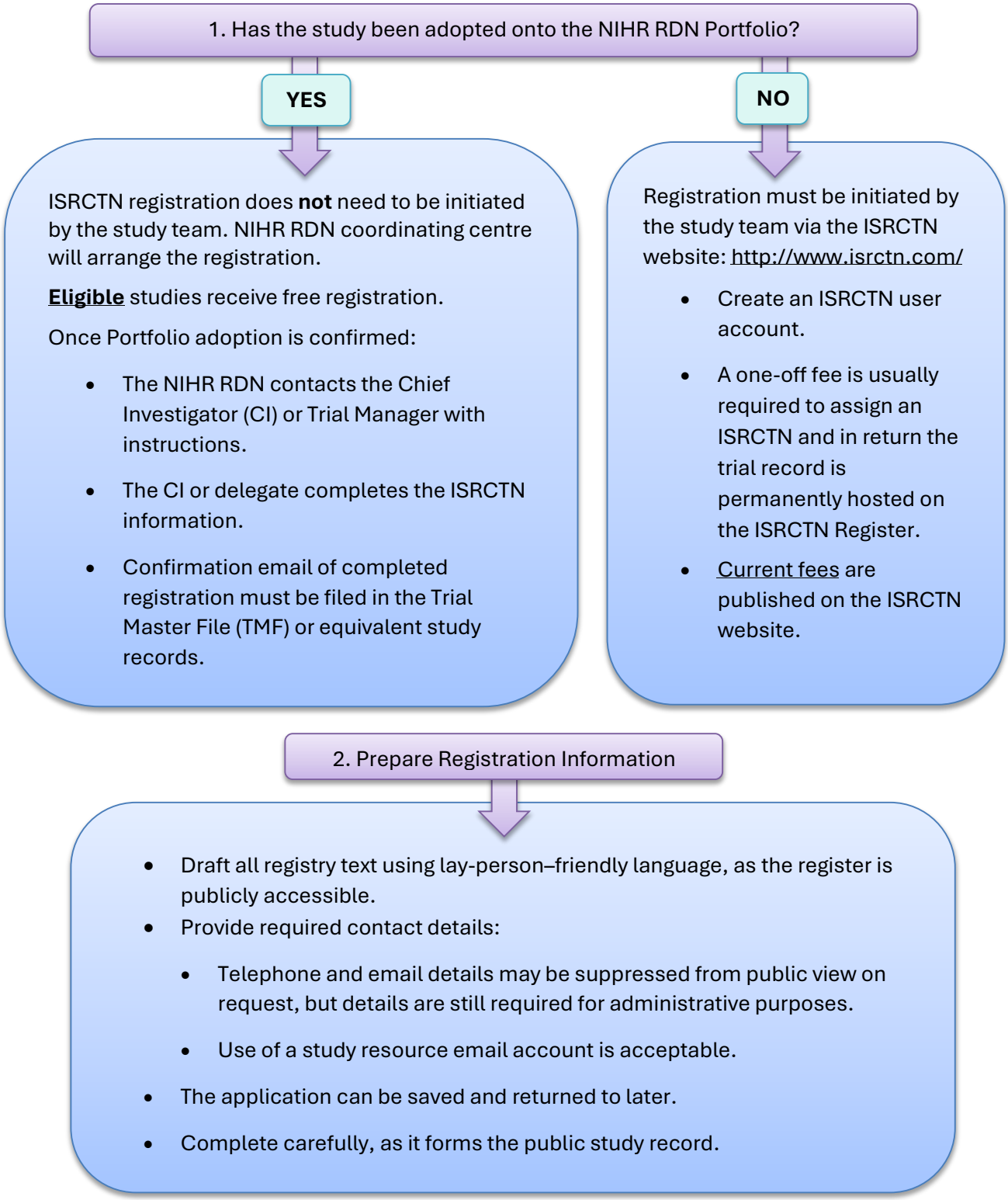
Deferral of trial registration is permitted in limited circumstances, such as adult phase I trials. Sponsors should contact the HRA at study.registration@hra.nhs.uk for advice before recruitment begins.

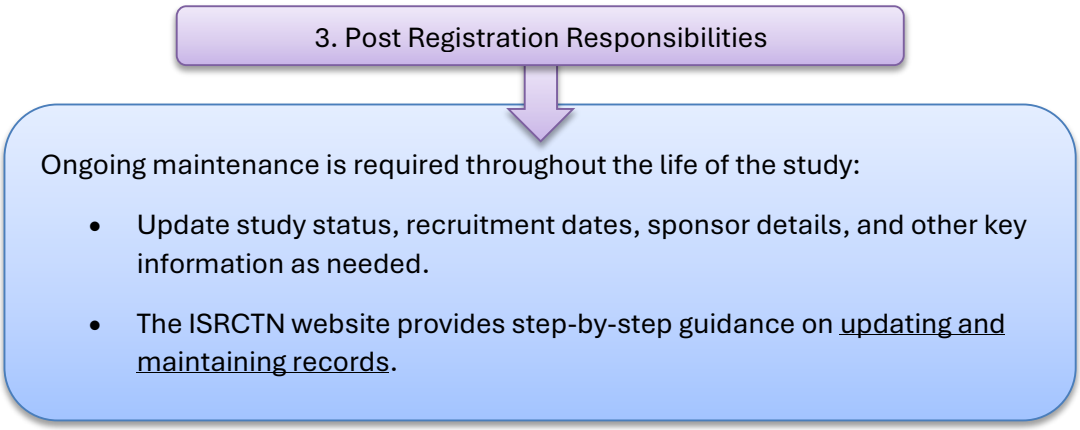
The registry number, if available, should be included in the application form when this is being prepared. If this is not available at the time of application, email the details to the MHRA at clintrialhelpline@mhra.gov.uk with subject line "Clinical Trial Registration" within six weeks of recruiting the first research participant. The REC should also be notified of the registration number as soon as possible.

CTIMPs with recruiting sites in the UK and EU or EEA, must be registered on both CTIS, and ISRCTN or ClinicalTrials.gov. This is because CTIS cannot accept or display information about the UK component of a multinational trial. As a result, the UK part of the study would not otherwise be publicly visible and needs to be registered separately.

7.1.2 Non-CTIMPs

A study can be registered on the ISRCTN website via the following link, where full guidance is provided: http://www.isrctn.com/. The registration process differs for studies depending on whether they are adopted onto the NIHR portfolio.


1. Has the study been adopted onto the NIHR RDN Portfolio?
YES
NO
ISRCTN registration does **not** need to be initiated by the study team. NIHR RDN coordinating centre will arrange the registration.
Eligible studies receive free registration.
Once Portfolio adoption is confirmed:
The NIHR RDN contacts the Chief Investigator (CI) or Trial Manager with instructions.
The CI or delegate completes the ISRCTN information.
Confirmation email of completed registration must be filed in the Trial Master File (TMF) or equivalent study records.
Registration must be initiated by the study team via the ISRCTN website: http://www.isrctn.com/
Create an ISRCTN user account.
A one-off fee is usually required to assign an ISRCTN and in return the trial record is permanently hosted on the ISRCTN Register.
Current fees are published on the ISRCTN website.
2. Prepare Registration Information
Draft all registry text using lay-person–friendly language, as the register is publicly accessible.
Provide required contact details:
Telephone and email details may be suppressed from public view on request, but details are still required for administrative purposes.
Use of a study resource email account is acceptable.
The application can be saved and returned to later.
Complete carefully, as it forms the public study record.



7.2 Making the results of research public

For CTIMPs (other than adult phase I trials), it is legal requirement that results are made publicly available within 12 months of study completion (as defined in the study protocol) in the public registry where the study was registered.

Before the introduction of automatic HRA registration (section 7.1.2), UK CTIMPs were registered on EudraCT to obtain a reference number for MHRA submission. For those legacy trials, results must still be uploaded to EudraCT. A brief confirmation email should then be sent to CT.Submission@mhra.gov.uk with the subject line "End of trial: result related information: EudraCT XXXXXXXXXXXX". The MHRA does not issue an acknowledgement, and a copy of the email should be retained in the TMF.

It is a good practice requirement that results from non-CTIMPs are also made publicly available within 12 months of study completion (as defined in the study protocol). This applies no matter whether the results are positive, negative, neutral or inconclusive. Posting results in a registry does not count as prior publication under ICMJE rules when limited to a short structured abstract or tables.

For studies managed by WCTU, alerts will be available for study teams three months prior to the reporting deadline. If results are not published in the required timelines, the issue will be escalated to the WCTU Director via the WCTU Governance Committee who will ensure appropriate actions are taken.

Summary results including key outcomes should be posted to the results section of the register(s) where the research project is registered.

Each trial should discuss the requirements for posting results and delegate the activity to a member of the team. This would usually require input from the study statistician with support from the CI.

If the register used does not have a results section, the results should be posted on a free-to-access, publicly available, searchable institutional website of the sponsor, funder or CI.

Where the main findings are also to be submitted for publication in a journal, this should be done within 12 months of study completion, to be published through an open-access mechanism in a peer-reviewed journal.

Key outcomes of CTIMPs and trial protocols must be made publicly available within 12 months of primary study completion.

7.3 Letting research participants know about the results of the research

Findings of the research should be made available to or provided to participants, or to their legal representatives, consultees, relatives or close friends (as appropriate), in a suitable format and within a reasonable timeframe, unless there is a justified reason not to do so. The HRA provides guidance on what information should be shared and how it should be communicated at the end of a study. G37 also provides guidance on patient accessibility and research funders may have specific requirements for reporting results which must be adhered to where applicable. There is no requirement to provide participants with details of their individual trial allocation in blinded trials. Unblinding is only appropriate where it is necessary for patient safety, where it is specified in the protocol, or where a participant specifically requests this and the CI/Sponsor agree it is appropriate and poses no scientific or safety risk to the trial.

Plans for communicating study findings should be described in the participant information so that participants understand when and how they can expect to receive this information. To meet UK GDPR and data protection requirements, participants should also be told how their contact details will be collected, stored and used for this purpose.

7.4 Making data or tissue from studies available for further research

It is an ethical and policy expectation that data and any tissue collected for a research project are made accessible for further research with appropriate safeguards. Major funders and the UK Policy Framework for Health and Social Care Research encourage responsible data sharing to maximise the value of research.

The ICMJE require the following as conditions for consideration for publication of a clinical trial report in member journals:

- Manuscripts submitted to ICMJE member journals must include a data sharing statement. This must specify:
  - whether individual de-identified participant data (and data dictionaries) will be shared
  - which data will be shared
  - whether related documents (e.g., protocol, statistical analysis plan) will be available
  - when the data will be available and for how long
  - access criteria, including who may access the data, for what analyses, and by what mechanism
- Clinical trials must include a data sharing plan in the trial's registration.
- If the data sharing plan changes after registration this should be reflected in the statement submitted and published with the manuscript and updated in the registry record.

See SOP 22 'Publication and Dissemination' for more details on data sharing and G27 gives guidance on data sharing statements.

The UKCRC have created comprehensive guidance on making datasets available; including reviewing data requests, preparing anonymised data packs, and secure transfer methods.

When a research project ends, continued storage of human tissue for future research is only lawful if one of the following arrangements is in place:

- ethical approval for a new project that covers storage and planned future use
- a research tissue bank with appropriate ethical approval, and a HTA licence where required

- transfer of the human tissue to a HTA-licensed establishment that is authorised to store human tissue for research.

This is in accordance with the Human Tissue Act 2004 and the HTA's Codes of Practice on research.

8 Associated templates and documents

Guidance on data sharing statements (G27)

Guidance on patient accessibility (G37)