Technology, Infrastructure and Environment Directorate Clinical Research Governance Team

Standard Operating Procedure

Research Transparency Requirements for Clinical Trials Sponsored by the University of Liverpool

SOP036

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Approved on behalf of ratifying committee Professor Tony Marson (Chair of Clinical Research Regulatory Oversight Committee)	**Date of Approval** 27th April 2026

Document Control

Issue Date	27/04/2026
Effective Date	28th April 2026
Review Date	27th April 2028
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Document History can be viewed on Ideagen Quality Management

Review Process Prior to Sign Off

Name of Committee	**Date**
Clinical Research Regulatory Oversight Committee – Version 1	23rd April 2026

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1. Introduction

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 (the Regulations) come into force on 28th April 2026.

These regulations introduce new legal requirements for research transparency for all Clinical Trials of Investigational Medicinal Products (CTIMPs) in the UK;

- register a clinical trial in a public registry before the recruitment of the first participant or within 90 days of approval of the clinical trial (whichever is sooner)
- publish a summary of the results within 12 months of the end of the trial
- offer to share a summary of the results with participants or relevant individuals (this should be in a suitable format and in a manner that's understandable to participants or those who may have provided consent on behalf of the participant or other relevant people)

Research transparency means that;

- patients, service users and carers can find opportunities to join studies
- researchers can build on previous research findings in their efforts to develop new and better treatments, and to identify the best ways for us to stay healthy and well
- health professionals, commissioners, policy makers and funders can use research findings to help make informed decisions

Many publishers, including the International Committee of Medical Journal Editors (ICMJE), require registration as a pre-condition of publication.

Failure to comply with the requirements to register or publish a summary of results (without any deferral or waiver) will constitute an offence under the new legislation and, if not corrected, may result in action being taken by the Medicines and Healthcare products Regulatory Agency (MHRA).

2. Scope of Procedure

This SOP provides details of the requirements for research transparency for University of Liverpool sponsored research.

3. Who

This SOP is aimed at Chief Investigators, students, trial coordinators and other members of University Staff involved in the registration process for University Sponsored research.

4. Registration of Clinical Trials

Clinical trials must be registered in a publicly accessible database before the recruitment of the first participant or within 90 days of approval of the clinical trial (whichever is sooner). This will be checked

by Sponsor as part of the Sponsor Permission to Proceed process (see also SOP004[1]). For clinical trials[2], it is a condition of a favourable ethics opinion. It is considered good practice for all other studies.

In certain circumstances the HRA may allow a deferral or waiver for registration;

- A deferral would postpone the timeframe to complete registration and other transparency requirements and is usually requested to protect confidential commercial information.
- A waiver will completely remove the requirement to adhere to the research transparency requirements. These are usually only issued in exceptional circumstances, for example, for reasons of national security or national defence.

If a trial plans to defer or waiver the research transparency requirements this must be discussed with the Sponsor before a formal request is submitted. If a deferral or waiver is granted, confirmation of this must be provided to Sponsor.

If the trial is a Phase 1 CTIMP only involving healthy volunteers, it will automatically be given a deferral for the transparency requirements for 30 months after the end of the trial.

This section provides details of potential registries that **may** be utilised to ensure compliance with the Regulations. As Sponsor, we recommend that only one registry is utilised for each piece of research. If multiple registrations are planned, this **must** be discussed and agreed with the Sponsor before registrations.

International Standard Randomised Controlled Trial Number (ISRCTN)

The **ISRCTN** Registry is the preferred partner of the Department of Health and Social Care and recommended by the University as Sponsor. ISRCTN accepts prospective and retrospective registration of all clinical research studies.[3]

ISRCTN also feeds into the NIHR Be Part of Research; an online service run by the National Institute for Health and Care Research (NIHR). Be Part of Research helps members of the public understand what research is, what it might mean to take part, and what research is currently happening across the UK.

Since 1 January 2022, all clinical trials of investigational medicinal products (CTIMPs) and combined trials of an investigational medicinal product and an investigational medical device submitted for combined review in the new part of IRAS are automatically registered on ISRCTN Registry. Further information, including information on registration of other types of

[1] Sponsorship Application and Approval Process

[2] A 'clinical trial' is:

- 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] Note, a fee may apply to register with ISRCTN, please ensure this is built into your grant.

clinical trial and also deferral of registration, can be found on the HRA website and the MHRA website.

ClinicalTrials.gov

As this is not a UK or EU Registry, The University of Liverpool, as a Sponsor organisation does not recommend use of clinicaltrials.gov unless this is **absolutely necessary** for the research, and there is a U.S. Food and Drug Administration (FDA) requirement to register with ClinicalTrials.gov.

Use of clinicaltrials.gov **must** be discussed and agreed with the Sponsor before registration of any research.

Please note - Clinicaltrials.gov is under the remit of the US Food and Drug Administration, and financial penalties can be imposed upon failure to submit required clinical trial information to the ClinicalTrials.gov data bank. It is the responsibility of the Chief Investigator to ensure that trial records are updated as required and be responsible for any financial penalties arising from failure to do so.

World Health Organisation (WHO) list of primary registries or the International Committee of Medical Journal Editors (ICMJE) list

If you wish to register your research with a register defined on either the World Health Organisation (WHO) list of primary registries or the International Committee of Medical Journal Editors (ICMJE) list, please contact Sponsor to discuss suitability of the registry before submitting your research. It should be noted, that this may not satisfy the transparency requirements under the Regulations.

EudraCT (European Union Drug Regulating Authorities Clinical Trials Database)

EduraCT was utilised to register CTIMPs conducted in the UK and EU from 1 May 2004 until 30 January 2025 under Directive 2001/20/EC. As of 31 January 2025, any EU/EEA trial on Investigational Medicinal Product(s) needs to be conducted under Regulation (EU) 536/2014. Any EU/EEA trial with a foreseen last patient last visit after this date should have been transitioned to the Clinical Trials Information System (CTIS). UK CTIMPs that are still open should ensure that the EduraCT record is updated as required and a summary of results is posted.

EU Clinical Trials Information System (CTIS)

For CTIMPs trials taking place in both the EU and the UK, registration with the EU Clinical Trials Information System (CTIS) will not satisfy trial registration requirement in the Regulations. This is because, although CTIS has been designated as a primary registry by WHO within the International Clinical Trials Registry Platform (ICTRP), it does not allow members of the public to identify trials taking place in the UK and therefore does not 'facilitate public access' to information about trials in the UK.

Confirming the first UK participant has been recruited

Sponsors will need to confirm the date that the first UK participant in a trial is recruited to show that the trial was registered within the given timeframes. Sponsors will do this by using the modification tool to submit a modification of an important detail which confirms the first recruitment has occurred.

5. Publication of Trial results

The Regulations state that a summary of results must be published within 12 months of the end of the trial. This applies to all CTIMPs that end on or after 28th April 2026, regardless of the date approvals were obtained and the trial started.

The end of trial definition should be documented in the protocol, and a planned end date will be provided to the Sponsor and all regulatory bodies. For most clinical trials this will be the date of the last visit of the last participant. It may also be the completion of any follow-up monitoring and data collection, as described in the protocol. For international studies, this is the end of study in all participating countries, not just in the UK. Any change to the end of study definition after approval has been given for the research should be notified as a modification to the appropriate review bodies.

The summary of trial results must be published in the same registry the trial was registered with, ensuring the procedures and requirements of that registry are adhered to. If a trial is registered with more than one registry, the full summary of trial results must be published in **each registry.** It is not acceptable to publish results in one registry and insert a link another registry, nor is it acceptable to publish the summary of results in another location and insert a link to that in the registry.

It is strongly encouraged that a plain language summary of the research findings is published with summary of trial results.

Any delays to publishing of the summary of trial results must be reported to the Sponsor as early as possible, so that notification to HRA can be made.

6. Providing a summary of results to participants

The Regulations state that any participants and/or relevant people must be offered a summary of the trial results in a way that can be understood by the public. This must be provided within 12 months of the end of the trial. Note, this summary should describe the trial's results as a whole, not any participant's individual results**.**

This applies to all CTIMPs submitted for approval from 28th April 2026, and although not required for other trials, it should be considered as a matter of good practice.

Sharing of results should be considered during trial design, ensuring that the requirements under the Regulations are complied with, as well as information governance requirements.

The population of the participant group(s) should also be considered when producing summary results, and ensure accessibility is considered across all groups. For example, if a trial recruited

children or adults lacking capacity, the format of the results may differ to that provided to adults. Consideration should also be given to provision of results to people other than participants, such as parents/guardians, carers or legal representatives.

The HRA has extensive guidance on how to prepare and provide participants with a summary of results. Please see the HRA website for more information.

7. Roles and Responsibilities

Sponsor (Sponsor Responsible Officer)

The Sponsor remains responsible for ensuring transparency requirements are adhered to. This will be overseen during the Sponsorship application process, and the study close down process, utilising FORM011[4] to ensure all requirements are met.

Chief Investigator (CI)

The CI is responsible for ensuring that transparency requirements are considered throughout the design of their study, and ensuring reporting of summary results is completed within 12 months of the end of the study.

8. Abbreviations

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
ICMJE	International Committee of Medical Journal Editors
ISRCTN	International Standard Randomised Controlled Trial Number
WHO	World Health Organisation

9. Associated Documents and References

Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

ISRCTN Registry

NIHR Be Part of Research

ClinicalTrials.gov

EudraCT (European Union Drug Regulating Authorities Clinical Trials Database)

EU Clinical Trials Information System (CTIS)

FORM011 - Sponsor End of Study Checklist

[4] Sponsor End of Study Checklist

10. Training and Resources

CIs, students, trial coordinators and other members of University Staff involved in clinical research should be aware of and familiar with this SOP. Training can be provided by the Clinical Research Governance Team upon request.

11. Monitoring and Audit

An internal audit of Clinical Directorate SOPs will be conducted at a minimum of every two years.