TAYSIDE MEDICAL SCIENCE CENTRE STUDY REGISTRATION & PUBLICATION POLICY: GUIDANCE FOR INVESTIGATORS

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1. Purpose

To give guidance on best practice with regard to the publication of papers, presentations, protocols, end of study reports and study results. This Policy should be read and understood in conjunction with the University of Dundee "Open Research Policy" and University of Dundee "Policy to Govern the Publication of Research".

2. Policy Objectives

This policy has been developed to provide guidance to researchers working within University of Dundee and/or NHS Tayside so that they meet the requirements set out in UK Policy Framework for Health and Social Care Research[1] and to ensure that:

- Clinical Trials of Investigational Medicinal Products (CTIMP) are conducted in compliance with the Medicines for Human Use (Clinical Trials) Act 2004 and subsequent amendments.
- All clinical research is conducted according to the principles of Good Clinical Practice (GCP).

3. Target Audience

Chief investigators (CI), local Principal Investigators (PI) and all other researchers conducting clinical research.

4 Study Registration

The World Health Organisation (WHO)[2] has made clear that the registration of interventional studies is a scientific, ethical and moral responsibility. All studies sponsored or co-sponsored by University of Dundee and NHS Tayside require to be registered with an appropriate register prior to review by a Research Ethics Committee (REC).

Additionally, it is a condition of a favourable NHS REC opinion that clinical trials be registered on an appropriate publicly accessible research register before recruitment of the first participant. The trials specified by REC as requiring registration are a CTIMP, a clinical investigation or other study of a medical device, a combined trial of an investigational medicinal product and an investigational medical device or another clinical trial to study a novel intervention or a randomised clinical trial (RCT) to compare interventions in clinical practice.

Appropriate registers are:

- the International Standard Randomised Controlled Trials Number (ISRCTN) Register
- ClinicalTrials.gov
- European Clinical Trials Database (EudraCT) conducted in the EU/EEA which is linked to the public EU Clinical Trials Register (EU CTR).

EudraCT registration is mandatory for CTIMPs sponsored in the UK that have investigator sites in the EU and registration must occur after Sponsorship is in place, but prior to an application for a Clinical Trial Authorisation (CTA) or Notification (CTN). The trial will be visible to the public via the EU CTR after the trial has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA).

ISRCTN and clinicaltrials.gov accept registration of all RCTs and any other research study designed to assess the efficacy of health interventions in the human population. Both are fully compliant with ICMJE[3] requirements and CONSORT[4].

There is a registration fee with ISRCTN, clinicaltrials.gov and EudraCT do not charge a fee.

Clinical trials registration with clinicaltrials.gov will be subject to Food and Drug Administration Amendments Act (FDAAA) rules and all the penalties that come with non-compliance.

Enrolment in more than one Register

Registration on multiple registry sites will not be advocated by the Sponsor unless under circumstances where multiple registration is unavoidable. For example, if the study drug has been packaged and labeled in the US and exported to UK specifically for research purposes, it is a requirement of the FDA that it be posted in clinicaltrials.gov.

5 Publishing Study Protocols

Publication of the study protocol is considered best practice and makes entirely transparent the research intentions before the study starts. The Biomed online journals publish

protocols as do journals such as Trials and they will usually be published without peer review or light-touch review if the study has received ethics approval and a grant from a major funding body. Protocols without funding or ethical approval will be peer reviewed.

6 Final Reports

Final reports should be written for all clinical research sponsored or co-sponsored by the University of Dundee and NHS Tayside. Final reports must be completed within 12 months of the end of study date and must be submitted to the NHS REC, the Sponsor, and where appropriate, the MHRA. Additionally, reports should be submitted to the Funder, where required.

6.1 NCTIMPs

NHS RECs do not specify a standard format for final reports, however as a minimum, the final report should specify if the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research, including any feedback to participants. A peer reviewed publication is acceptable in lieu.

6.2 CTIMPs

The ICH Guideline for Good Clinical Practice (GCP) E6 (R2)[5] section 4.13 states that Investigators, upon completion of a trial, should inform the Sponsor Institution and that the Investigator or Institution should provide the REC with a summary of the trial's outcome, and the regulatory authority with any reports required.

The ICH Guideline E3, Structure and Content of Clinical Study Reports[6], provides detailed guidance on the structure and content of the final report. Where the trial is international, this is the end of study in all participating countries and not just in the UK. However, the Sponsor, REC and MHRA should be voluntarily advised where the UK arm of a trial ends in advance of the conclusion in all Member States.

A final report - the Clinical Trial Summary Results- must be submitted to the MHRA, and to NHS REC within 12 months of the end of trial (or 6 months for paediatric trials)[7]. A copy of the report must also be sent to Sponsor and an email notification sent to MHRA to confirm upload.

7. Study Results

Investigators who register studies on ISRCTN or clinicaltrials.gov must ensure that the study record is maintained and updated in a timely manner. Information must include final enrolment numbers achieved and the date of study end. Results must be uploaded to the public registers within twelve months of the end of study date. The end of study date for interventional trials should be last participant, last visit (LPLV)[8], or where appropriate, database lock. The record should then be annotated as complete.

8. Authorship of Publications and Presentations

The International Committee of Medical Journal Editors (ICMJE) developed recommendations 'to review best practice and ethical standards in the conduct and reporting of research and other material published in medical journals, and to help authors, editors, and others involved in peer review and biomedical publishing create and distribute accurate, clear, unbiased medical journal articles'[1].

All authors of published or presented papers must fulfil at least three criteria:

- Each author should have made substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data.
- In addition, each author should have critically reviewed successive drafts of the paper.
- It is preferable that all authors be familiar with all aspects of the work. Some authors' contributions may be limited to specific aspects of the work as a whole but fulfil at least three criteria from above. Each author should be able to defend his/her contribution.

Authors should refer to the University of Dundee "Policy to Govern the Publication of Research." for further guidance.

References

1. UK Policy Framework for Health and Social Care Research. (Last updated 4 November 2022).
2. WHO Statement on Public Disclosure of Clinical Trial Results.
3. ICMJE Recommendations. Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. December 2016.
4. Kenneth F Schulz, Douglas G Altman, David Moher, for the CONSORT Group. CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010; 340:c332 doi:10.1136/bmj.c332.
5. ICH Guideline for Good Clinical Practice (GCP) E6(R2 (2016).
6. ICH Guideline Structure and Content of Clinical Study Reports E3 (1996).
7. Communication from the Commission — Guidance on the information concerning paediatric clinical trials to be entered into the EU Database on Clinical Trials (EudraCT) and on the information to be made public by the European Medicines Agency (EMEA), in accordance with Article 41 of Regulation (EC) No 1901/2006 (2009/C 28/01).
8. Commission Guideline — Guidance on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of

Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006 (2012/C 302/03).

DOCUMENT HISTORY

History prior to 2021 is in the archived Policies available from TASC Quality Assurance Dept.

Version Number:	**Reviewed By (Job Title):**	**Effective Date:**	**Details of editions made:**
10	Patricia Burns (Senior Research Governance Manager)	03/02/2023	Section 6.2.1 to 6.2.3 removed. Text refreshed throughout and references updated. UK Policy Framework for Health and Social Care Research added to the references section. All links to websites removed.
11	Patricia Burns (Senior Research Governance Manager)	03/02/2025	References to UoD policies amended so that they match with the language used on the policies themselves. EudraCT registration is mandatory for CTIMPs sponsored in the UK that have investigator sites in the EU added to section 4.

APPROVALS

Approved by:	**Date:**
Professor Linda Martindale, Dean, School of Health Sciences, University of Dundee, on behalf of TASC Research Governance and Oversight Committee	23rd Jan 2025
Approved by:	**Date:**
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	3rd Feb 2025