STANDARD OPERATING PROCEDURE FOR REGISTERING AND REPORTING HEALTHCARE RESEARCH IN A PUBLICLY ACCESSIBLE DATABASE

SOP NUMBER:	TASC SOP061 v5
AUTHOR:	Tracy Petrie
ISSUE DATE:	03 Sept 2022
EFFECTIVE DATE:	03 Sept 2022
REVIEW DATE:	03 Sept 2024

1. PURPOSE

This Standard Operating Procedure (SOP) describes the processes to be followed to ensure compliance with the Declaration of Helsinki 2013 statement that all Healthcare Research involving human subjects must be registered in a publicly accessible database before recruitment of the first participant and results made publicly available.

2. SCOPE

This SOP applies to all research sponsored by University of Dundee and/or NHS Tayside

3. RESPONSIBILITIES

IMPORTANT INFORMATION
To meet World Health Organisation (WHO) requirements for transparency and publication, it is only necessary for a trial to be registered once, in either a Primary Registry or an International Committee of Medical Journal Editors (ICMJE) approved registry.

Chief Investigator (CI) is responsible for:

- Registering the trial on a recognised public register after sponsor approval.
- Ensuring the information database in which the project is registered is kept up to date and accurate at all times.
- Uploading the end of trial results in the database in which the project is registered.
- Providing Sponsor with the registration details.

Sponsor is responsible for:

- Ensuring the registration and reporting of trials on a register have been completed.
- Identifying any locally sponsored trials which have not yet reported results according to WHO requirements for transparency and publication.

4. PROCEDURE

4.1 Registration of Clinical Trials

4.1.1 All healthcare research must be registered in an appropriate approved publicly accessible database.

4.1.2 Clinical Trials of Investigational Medicinal Products **(**CTIMPs) and combined trials of an Investigational Medicinal Product (IMP) and an investigational medical device (IMP/device trials) will be automatically registered in International Standard Randomised Controlled Trial Number Registry (ISRCTN) via Integrated Research Application System (IRAS), free.

4.1.3 Other Clinical Trials involving human subjects must be registered either in ISRCTN (cost may apply) or any other approved register (cost may apply).

4.1.4 If there is no suitable register for the project this must be stated clearly in the IRAS application.

Studies may not be accepted for publication if not registered.

4.2 Updating Registers

4.2.1 Registers must be kept up to date throughout the trial.

4.2.2 The results of the trial must be reported and uploaded to the registry that the trial was registered on.

4.2.3 The results must be reported within 12 months of the End of Trial Declaration or End of Study Declaration and within 6 months for Paediatric Trials.

4.2.4 Any delays in the uploading of the Clinical Trials results must be reported to the Sponsor and to the Medicines and Healthcare products Regulatory Agency (MHRA) for CTIMPs.

4.3 Clinical Trials already registered on EudraCT

Trials registered before 31st Dec 2020 can continue to have their results posted in EudraCT. Refer to https://medregs.blog.gov.uk/2021/12/22/the-past-the-present-and-the-future-of-clinical-trials-transparency-in-the-uk/

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
ICMJE	International Committee of Medical Journal Editors
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
ISRCTN	International Standard Randomised Controlled Trial Number Registry
MHRA	Medicines and Healthcare products Regulatory Agency
SOP	Standard Operating Procedure

TASC Tayside Medical Science Centre
WHO World Health Organisation

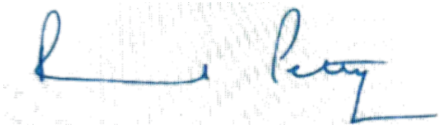
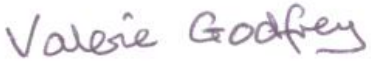
6. ASSOCIATED DOCUMENTS & REFERENCES

None.

7. DOCUMENT HISTORY

Version Number:	Reviewed By (Job Title)	Effective Date:	Details of editions made:
1	Tracy Petrie	22/11/2018	New.
2	Tracy Petrie (Research Registry Data Officer) & Ashley Morrison Research Group Facilitator)	19/04/2019	Addition of Doc Ref: 124 Guide for Registering and Reporting in EudraCT.
3	Tracy Petrie	03/09/2020	Added new section to clarify Sponsor position on registration. Instructions removed for ClinicalTrials.gov as sponsor does not approve registration on this register.
4	Tracy Petrie (Research Registry Data Officer)	29/01/2021	Uploaded to new TASC SOP template which shows the new TASC website in the footer. Physical scan converted to electronic pdf as a requirement for upload to new TASC website.
5	Tracy Petrie (Research Registry Data Officer)	03/09/2022	SOP rewritten due to the changes of CT registration. CTIMPs will be automatically registered in ISRCTN via IRAS. Section on EudraCT reporting removed as no longer in the EU. Doc Ref 124 (Registering and Reporting in EudraCT) removed.

8. APPROVALS

Sign		Date
APPROVED BY:	Professor Russell Petty, R&D Director, NHS Tayside	
Signature		30 Aug 2022
APPROVED BY:	Dr Valerie Godfrey, TASC QA Manager, Chair of Clinical Research Guidelines Committee	
Signature		29 Aug 2022