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

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1. PURPOSE

This SOP describes the processes to be followed to ensure compliance with the Declaration of Helsinki 2013 statement that every research study involving human subjects must be registered in a publicly accessible database.

For the purpose of this SOP, the Sponsor recognises Public Registers as those that meet the requirements of the Primary Registries in the World Health Organisation (WHO) listed registers and the International Committee of Medical Journals List.

2. SCOPE

This SOP applies to the following:

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

3 RESPONSIBILITIES

IMPORTANT INFORMATION

For UK sponsored CTIMPs, registration is mandatory on European Clinical Trials Database (EudraCT).
To meet WHO requirements for transparency and publication, it is only necessary for a trial to be registered once, in either a Primary Registry i.e. EudraCT 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.
- Ensuring the information database in which the project is registered is kept up to date and accurate at all times.

Sponsor is responsible for:

- Ensuring the reporting of trials on a register.
- For conducting internal audits and putting in place safeguards to ensure that results are reported on time.
- Identifying any locally sponsored trials which have not yet reported results according to WHO requirements for transparency and publication.

4. PROCEDURE

4.1 EudraCT

A EudraCT number is the mandatory reference number allocated by the European Medicines Agency (EMA) for CTIMPs
Application for a EudraCT number should be made around the time of Sponsorship, and will be confirmed via the EudraCT website. This unique number remains with the trial throughout its lifetime, and will enable access to upload results at the End of Trial.

4.1.1 To generate the number some basic information is required for the request form:

- Sponsor/R&D reference number. *This is located on the Confirmation of Sponsorship letter.*
- Chief Investigator name.
- E-mail to which the EudraCT number will be sent.

4.1.2 The Request Form requires basic trial details:

- Whether the clinical trial is contained in a Paediatric Investigation Plan (PIP).
- Whether the clinical trial will be conducted in a third country (outside of the EU/EEA).
- The Member States where it is anticipated that the trial will be run.

4.1.3 Once the form is submitted the system will automatically assign the number and send a confirmation email.
The e-mail is called "EudraCT Receipt" and is sent to the email entered in the request form.

The EudraCT number has the format YYYY-NNNNNN-CC, where:
YYYY is the year in which the number is issued.
NNNNNN is a six digit sequential number.
CC is a check digit

4.1.4 Forward a copy of this email to TASCgovernance@dundee.ac.uk to be held in the Sponsor File
Print and retain a copy in the Investigator Trial Master File.

4.2 Clinicaltrials.gov

4.2.1 US National Register.
Can be used for CTIMPs and non-CTIMPs
US journals may require a clinicaltrial.gov number to ensure publication.
Currently free to register.

4.2.2 Application for a clinicaltrials.gov number (NCT) is made via the clinicaltrials.gov website. https://clinicaltrials.gov/

An account must be opened to enable this.

4.2.3 In order to obtain an account: contact TASCgovernance@dundee.ac.uk.
An email will be sent by Clincialtrials.gov directly to the user with their account details.

4.2.4 Once the account is set-up, the protocol information can be entered onto the website.

The website requires identification of the following:

Responsible party: CI: Must review the entries and *RELEASE* the record.

Record owner: CI, Trial Manager or delegate: Completes the forms and updates study status (*Not recruiting/recruiting/closed to recruitment*).

4.2.5 The forms must be completed and users are encouraged to submit all data elements in order to provide a complete description of the study.
The record must be *RELEASED* to enable review by Clinicaltrials.gov.
A ClinicalTrials.gov staff member will review the study record before it is made available to the public.
The Responsible Party may be asked to clarify items or make corrections to the record before being made public.
This review process may take up to a few days.
After a record is *RELEASED* and is accepted by review staff, and there are no outstanding queries, the trial, including its NCT Number, will be available on ClinicalTrials.gov within 2–5 business days.

Note: To be compliant with registration, the protocol must show as "*Released to the Public*"

4.3 International Standard Randomised Controlled Trial Number Registry (ISRCTN)

4.3.1 UK National Register
Can be used for CTIMPs and non-CTIMPs
Currently free to register for studies which are eligible for inclusion on the NIHR CRN portfolio. Other projects may be registered for a fee.

4.3.2 To apply for an ISRCTN, go to click on Register (http://www.isrctn.com/login) on the home page or go to the login section.

An application has 4 stages:

- Trial details
- Contacts
- Sponsors
- Funders

4.3.3 Once you have completed the required fields, and submitted the application, a member of the ISRCTN team will contact you with any questions on the details of your study.
Once the review is complete and a unique identifier is issued it is included in the ISRCTN registry.

4.3.4 Forward evidence of this registration to TASCgovernance@dundee.ac.uk

4.4 Updating Registers

4.4.1 EudraCT

- Requires no update during the lifetime of the trial following initial registration. After submission of the EudraCT application to the MHRA any amendments will be automatically updated if an amended EudraCT form is submitted to MHRA.
- Edits may be required for example to record additional international sites.
- End of trial results are mandatory within one year of the end of trial date and within 6 months for paediatric studies.
- To obtain authority to upload end of trial results, contact TASCgovernance@dundee.ac.uk for an assignment letter, see associated Doc Ref: 124 Guide for Registering and Reporting in EudraCT, this letter is required to be uploaded onto the website and data upload cannot occur without this.
- Notify TASCgovernance@dundee.ac.uk once entry is complete.
- This confirmation of the upload will be retained in the Sponsor Files.

4.4.2 Clinicaltrials.gov

Requires mandatory updating of study status e.g.

- Not recruiting
- Withdrawn
- Terminated
- Actively recruiting
- Closed to recruitment
- Completed

End of trial results are mandatory within one year of the end of trial date.
Notify TASCgovernance@dundee.ac.uk once entry is complete.
This confirmation of the upload will be retained in the Sponsor Files.

4.4.3 ISRCTN

- Requires researcher to proactively contact info@isrctn.com to ensure they are aware of any changes to the trial.
- Basic trial results to be uploaded within one year of end of trial date.
- Requires notification of publications related to the trial.

5 ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
EEA	European Economic Area
EMA	European Medicines Agency
EU	European Union
EudraCT	European Clinical Trials Database
ICMJE	International Committee of Medical Journal Editors
IRAS	Integrated Research Application System
ISRCTN	International Standard Randomised Controlled Trial Number Registry
NCT	clinicaltrials.gov number
NHST	NHS Tayside (Tayside Health Board)

PIP	Paediatric Investigation Plan
SOP	Standard Operating Procedure
WHO	World Health Organisation
UoD	University of Dundee

6. ASSOCIATED DOCUMENTS & REFERENCES

Doc Ref: 124 Guide for Registering and Reporting in EudraCT

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI Ethical Principles for Medical Research Involving Human Subjects.

Medicines for Human Use (Clinical Trials) Regulations 2004. *It is assumed that by referencing the principal regulations, all subsequent amendments made to the principal regulations are included in this citation.*

7. DOCUMENT HISTORY

Version Number:	Reviewed By (Job Title)	Effective Date:	Details of editions made:
1.0	Tracy Petrie	22/11/2018	New.
2.0	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.

8. APPROVALS

Sign		Date
APPROVED BY:	Professor Jacob George, R&D Director, NHS Tayside	
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