STANDARD OPERATING PROCEDURE FOR WRITING A PROTOCOL TO GOOD CLINICAL PRACTICE FOR CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS

SOP NUMBER:	TASC SOP014 v9
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1. PURPOSE

This document describes the procedure for writing a research protocol that complies with the principles of Good Clinical Practice (GCP) for Clinical Trials of Investigational Medicinal Products (CTIMPs).

2. SCOPE

This document applies to CTIMPs sponsored or co-sponsored by the University of Dundee (UoD) and/or NHS Tayside (NHST). The SOP applies to all Investigators writing a protocol for a CTIMP.

3. RESPONSIBILITIES

Chief Investigator (CI): Designing and writing the protocol compliant with the principles of GCP and relevant regulations, appropriate to the research.

Sponsor: Ensure any amendments to the protocol are managed correctly.

Research Monitors: Monitoring researcher against protocol.

4. PROCEDURE

4.1 The CI or delegate must use the Health Research Authority (HRA) Protocol Template for CTIMPs available on the HRA website, unless previously discussed with the Sponsor.

4.2 All protocols must be version controlled and the version number, date, study title (or acronym), Integrated Research Application System (IRAS) number and page number must be on all pages. Refer to TASC SOP on version control.

4.3 The Approval page for fully approved protocols must be signed and dated by the CI, the individual responsible for statistical review and any other appropriate trial staff such as Principal Investigator(s) (PI) prior to distribution. The signature of the CI, as a minimum, must be present prior to submission to the Medicines & Healthcare Products Regulatory Agency (MHRA).

4.4 By signing the protocol the individuals concerned are making a formal agreement to adhere to it at all time.

4.5 Where appropriate, the protocol may refer to information contained in other documents e.g. in the Operations Manual, the Summary of Product Characteristics (SmPC), Investigator's Brochure (IB), local handling procedures, storage etc. Trial Steering or Data Monitoring Committee (DMC) remit and membership.

4.6 All planned amendments to the protocol must be submitted in the first instance to the Sponsor, via the TASC Research Governance Manager. Refer to TASC SOP on amendments to CTIMPs.

4.7 All fully approved amended protocols are subject to the processes detailed in 4.1 - 1.7 above.

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trials of Investigational Medicinal Products
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
HRA	Health Research Authority
IB	Investigators Brochures
IRAS	Integrated Research Application System
MHRA	Medicines & Healthcare Products Regulatory Agency
NHST	NHS Tayside
PI	Principal Investigator
SmPC	Summary of Product Characteristics
TASC	Tayside Medical Science Centre
UoD	University of Dundee

6. ASSOCIATED DOCUMENTS & REFERENCES

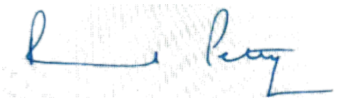
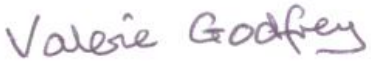
Refer to the Research planning/Protocol section of HRA's website for Protocol guidance and template for use in a Clinical Trial of Investigational Medicinal Product (CTIMP).

7. DOCUMENT HISTORY

Version Number:	Reviewed By (Job Title)	Effective Date:	Details of editions made:
History of reviewers prior to 2014 is detailed in the archived SOPs			
5	Catrina Forde (Senior RGM)	06/12/2014	Updated to reflect current practices.

6	Catrina Forde (Senior RGM)	06/12/2016	Updated to reflect current practices.
7	Patricia Burns (Senior Research Governance Manager)	26/11/2018	Amendment to make mandatory use of HRA Protocol template. Addition of Responsibilities section. Correction of Abbreviations. Removal of Policy (not related to this SOP). Removal of text now covered in HRA Protocol template.
8	Patricia Burns (Senior Research Governance Manager)	23/11/2020	Biennial review. Section 4.2 & 4.3 combined, text refreshed. Uploaded to new SOP template and new TASC website address added to the footer.
9	Patricia Burns (Senior Research Governance Manager)	23/11/2022	No changes required at this review.

8. APPROVALS

Sign		Date
APPROVED BY:	Professor Russell Petty, R&D Director, NHS Tayside	
Signature		14th November 2022
APPROVED BY:	Dr Valerie Godfrey, TASC QA Manager, Chair of Clinical Research Guidelines Committee	
Signature		14 Nov 2022