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

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| SOP NUMBER: | TASC SOP014 v10 |
| AUTHOR: | Patricia Burns |
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| REVIEW DATE: | 20 Nov 2026 |

## 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 Standard Operating Procedure 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 times.

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

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| 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 |
| SOP | Standard Operating Procedure |
| 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

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

| Version Number: | Reviewed By (Job Title): | Effective Date: | Details of editions made: |
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| 9 | Patricia Burns (Senior Research Governance Manager) | 20/11/2024 | No changes required at this review. |
| 10 | Patricia Burns (Senior Research Governance Manager) | 20/11/2024 | No changes required at this review. |

**8. APPROVALS**

| Approved by: | Date: |
|---|---|
| Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee | 18 Nov 2024 |