

STANDARD OPERATING PROCEDURE

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Review and Approval of Protocols and Amendments

R&D/S/013/1.0

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VERSION

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Approved By:

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Date

Effective Date:

Review date:

Copy Number:

Review and Approval of Protocols and Amendments

1. PURPOSE AND SCOPE

As part of the Clinical Trials (CTIMPS) Approval Process, R&D should review all protocols and substantial amendments submitted by Investigators to ensure that they are appropriate for the studies being undertaken.

This SOP describes this review process within R&D.

2. ASSOCIATED DOCUMENTS

Template	R&D Template Protocol - R&D/T/013a
Form	Amendment Checklist – R&D/CF/013a

3. APPLICABILITY

This SOP applies to protocols for all CTIMP research studies sponsored by Cambridge University Hospitals NHS Foundation Trust (CUHNFT) or jointly sponsored by CUHNFT and the University of Cambridge. The procedure can also be used for non-CTIMP studies.

4. PROCEDURES

4.1 PROTOCOL REVIEW

4.1.1 Protocols should be written by Investigators either in their own format or using the R&D Template (Appendix 1). They should contain all elements required by ICH GCP and should be designed to safeguard the health and safety of participants.

4.1.2 Prior to obtaining MHRA, Ethical and R&D approval the protocol should be submitted to the R&D Department for review. The protocol should be reviewed by the Clinical Trials Manager, or designee.

4.1.3 The reviewer should check key aspects of the protocol to ensure that it meets either the current R&D template (if this has been used), or that it contains all the elements required by ICH GCP. The following is a summary of key aspects that should be included (but not limited to) in a protocol and these should be considered during the review.

- Introduction and general information
- Trial objectives and purpose
- Selection and withdrawal of subjects
- Treatment of subjects
- Safety/Adverse Event reporting
- Endpoints
- IMP and placebo
- Statistics
- Direct access to source data/documents
- Quality control and quality assurance
- Reporting/Publication policy

4.1.4 Any comments made by the reviewer can be annotated/tracked changes on the protocol and sent back to the Investigator.

4.1.5 The reviewer should sign and date on the front page of the protocol or send an email to confirm the review.

Review and Approval of Protocols and Amendments

4.2 AMENDMENTS

4.2.1 Amendments are changes made to the trial, the protocol and/or supporting documents, after approvals have been given by MHRA, Ethics and R&D.

4.2.2 There are two types of protocol amendments:

Substantial
Minor

4.2.3 A 'substantial amendment' is defined as an amendment to Clinical Trial/REC application, or to the protocol or any other supporting documentation, that is likely to affect to a significant degree:

- the safety or physical or mental integrity of the subjects of the trial;
- the scientific value of the trial;
- the conduct or management of the trial; or
- the quality or safety of any investigational medicinal product used in the trial.

4.2.4 The Trust has delegated the responsibility for deciding whether an amendment is substantial or not to the CI who should submit appropriately. For CTIMPs the "Notification of a Substantial Amendment to a Clinical Trial on a medicinal Product for Human Use to the Competent Authorities and for opinion of the Ethics Committees in the Community" form should be used:

<https://eudract.emea.europa.eu/document.html>

4.2.5 All substantial amendments should be notified and approved by either the MHRA only, main REC only, or to both, prior to implementation of the amendment. Either way, all substantial amendments should be sent to R&D. Minor amendments also require review by the R&D Department, but may not require notification to another relevant body, depending on what will be amended.

4.2.6 Upon receipt of the substantial amendment, R&D staff should review the amendment to:

- ensure that it meets the needs of the study and that subjects safety and rights are still being protected.
- to check if there are any changes to governance or specific changes to the protocol which may have an effect on other support areas that may be involved in the trial e.g. pharmacy, radiology etc.

4.2.7 The documentation for these amendments will be checked and any additional documents/approvals will be requested. For Oncology trials, pharmacy issues can be approved by the Clinical Trials Pharmacist, Adult Oncology. For other trials, pharmacy changes can be approved by the Principal Pharmacist Technical Services or Principal Technician Clinical Trials.

4.2.8 The amendment checklist (see appendix 2) should be completed and when all checks are finalised, the checklist and the approval letter is passed to the R&D Manager to be approved and signed. All EUCTs must have a letter of approval rather than an email.

4.2.9 The amendment approval letter template can be obtained from the documents section on ReDA.

Review and Approval of Protocols and Amendments

5. ILLUSTRATIONS/APPENDICES

APPENDIX 1 – R&D Protocol Template
APPENDIX 2 – Amendment Checklist

6. CHANGES SINCE LAST VERSION

Description of changes	
<i>Section Ref:</i>	<i>Brief description of change</i>
NA	New SOP