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SOP 340 Clinical Trial Reporting

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
Division responsible for document:	Research & Development
Key words:	Clinical Trial Reporting
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Description of changes:	New requirements for end of trial reports Minor amendments

This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

Copies printed from the website are only valid on the day of printing.

SOP 340 Clinical Trial Reporting

1. Contents

2. Definitions of Terms Used / Glossary

APR	Annual Progress Report
CI	Chief Investigator
DSUR	Development Safety Update Report
HRA	Health Research Authority
ICH GCP	International Conference on the Harmonisation of Good Clinical Practice
MHRA	Medicines and Healthcare Products Regulatory Agency
PI	Principal Investigator
R&D	Research and Development
REC	Research Ethics Committee
SI	Statutory Instrument
SOP	Standard Operating Procedure

3. Objectives

To ensure a robust reporting procedure for formal clinical trial reporting to the Sponsor, REC and MHRA as well as the procedures for the reporting of results in other reports and publications in accordance with ICH GCP E6/SI 2004/1031 and 2006/1928

4. Scope

This SOP applies to all research studies which NNUH and UEA have participated in.

5. Purpose

To provide clear guidance to the CI / PI and study teams for preparing a report, the content and responsibilities.

6. Reporting

It is vital that the Sponsor, Research Ethics Committee (REC)/Health Research Authority (HRA) and Medicines and Healthcare Products Regulatory Agency (MHRA) are informed of:

Adverse Events

- The Chief Investigator (CI) shall report all Serious Adverse Events to the Sponsor, in accordance with the following SOPs:
- SOP 205 Adverse Events: Identifying, Recording and Reporting for CTIMPs Sponsored by the Norfolk and Norwich University Hospitals NHS Foundation Trust
- SOP 206 Adverse Events: Identifying, Recording and Reporting adverse events for Non-CTIMP Non-Device Healthcare Research Studies
- SOP 207 Adverse Events: Identifying, Recording and Reporting Adverse Events for Device Trials

Annual Reports

CTIMPS

- A DSUR should be submitted annually to the REC and MHRA. The CI has overall responsibility for the information and must sign it, but preparation of the document is often delegated e.g. if CTU involved.
- In addition an annual progress report (APR) should also be sent to the REC/HRA

Non-CTIMPS

- For studies that are more than two years in duration and for Research Tissue Bank and Research Databases, an annual progress report must be sent to the REC/HRA. The form is available at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/progress-reports/

The CI shall report all Adverse Events to the Sponsor, REC/HRA and MHRA in accordance with the Sponsor Delegation of Responsibilities

Breach to Protocol or GCP

- Sponsor oversight is required for serious breach reporting to REC/HRA and/or MHRA
- Follow SOP 210 Managing Protocol and Regulatory Non-Compliance including Serious Breaches

Formal Declaration of the End of Clinical Trials

- The definition of the end of the study must be documented in the protocol. In most cases, this will be the date of the last visit of the last participant or the completion of any follow-up monitoring and data collection described in the protocol
- If there is any change to this definition, the CI must notify this as a substantial amendment
- SOP 335 Research Project Closure (Including Procedure for Suspension or Early Termination)

7. End of Trial Study Reporting

For clinical trials of investigational medicinal products (CTIMP)

- A summary of the final research report must be issued to the REC, MHRA and Sponsor within 12 months of the end of the study

For Medical Device Trials

- The MHRA may request a copy of the final report of a clinical investigation of a device
- It is likely that a copy would particularly be requested under certain circumstances, e.g. where a serious adverse event has occurred associated with a CE-marked device which had undergone clinical investigation authorised by the UK Competent Authority, or where a novel technology has been investigated

For Non-CTIMP Trials

- The CI will submit a summary of the study within 12 months of the end of the study to the REC and Sponsor

8. End of trial report format guidance

If the application was submitted via combined review, the final report should be completed and submitted in the new part of Integrated Research Application System (IRAS).

All other project-based research reviewed by a REC, should use the webform on the HRA website.

The CONSORT guidelines www.consort-statement.org should be adhered to when preparing a manuscript for a clinical trial relating to a randomised study. This ensures that all relevant information about the trial is reported in the publication.

9. Studies in follow up

If a new event occurs after the closure of the trial that:

• Is likely to change the risk / benefit analysis of the trial and could still have an impact on the study participants:
  • The CI should notify the Sponsor to provide Sponsor oversight
  • The REC and (MHRA if applicable) must be notified by the CI / Sponsor with a proposed course of action

10. Reporting of Study Results

⇩	Reporting of trial results shall be governed by a publication policy clearly defined in the protocol and with guidance to the CI and study team from the Data Monitoring Committee, Trial Management Group and Trial Steering Committee as appropriate.
⇩	Results of clinical trials must be disseminated, not only to the research community, but also to the general public
⇩	The exact format of any report or publication will depend on the individual study requirements, the intended audience and any technical requirements of the publisher – see section 8
⇩	After data lock-down (see **SOP 815 – Clinical Data Management System – Locking and Unlocking the Database**), analysis of all study data should be in line with the protocol objectives and endpoints
⇩	Analysis shall follow the data analysis plan prior to any unblinding of study data (if applicable)
⇩	All outcome measures as stated in the protocol will be fully analysed

	It is important that the study analysis is carried out promptly after the declaration of study end, to ensure the 12-month reporting deadline is met
	The study team must undertake appropriate review and quality control measures of the analysis output before its dissemination or publication
	The CI, Trial Manager and Statistician will review the analysis output involving additional review mechanisms such as member(s) from the Data Monitoring Committee, REC and/or funding body to demonstrate validity, good practice, and the publisher's guidelines
	For studies involving a health economic analysis, the analysis output shall also be reviewed by the Health Economist

Where no formal alternative guidance exists from a publisher or funder, the study team is asked to prepare study reports using the following headings (where applicable):

- Title
- Synopsis
- Table of contents
- Abbreviations
- Ethics
- Study structure
- Introduction
- Objectives
- Investigational Plan
- Findings
- Conclusion

11. References and Related Documents

References
ICH GCP E6/SI 2004/1031
ICH GCP E6/SI 2006/1928

SOP No.	SOP Title
SOP 205	Adverse Events: Identifying, Recording and Reporting for CTIMPs Sponsored by the Norfolk and Norwich University Hospitals NHS Foundation Trust
SOP 206	Adverse Events: Identifying, Recording and Reporting adverse events for Non-CTIMP Non-Device Healthcare Research Studies
SOP 207	Adverse Events: Identifying, Recording and Reporting Adverse Events for Device Trials
SOP 210	Managing Protocol and Regulatory Non-Compliance including Serious Breaches
SOP 335	Research Project Closure (Including Procedure for Suspension or Early Termination)
SOP 815	Clinical Data Management System – Locking and Unlocking the Database

12. Approval

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13. Reason for new version and Training Implication

This SOP replaces the previous version number V2

Changes made	
Reason	New requirements for end of trial reports Minor amendments
Training Implication	**No**
Actions required	• Review changes to procedure