JOINT RESEARCH AND DEVELOPMENT OFFICE

Somers Clinical Research Facility

End of Study Reporting Requirements for Clinical Trials

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Revision History			
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1. Scope /Background

This SOP is applicable to all the clinical trials sponsored, co-sponsored by Great Ormond Street Hospital. The SOP is applicable to Chief Investigators (CI), PIs, and delegated trial team members involved in Trust-sponsored CTIMPs and the Joint R&D Office Clinical Trials Team with responsibility for performing sponsor activities on behalf of the Trust.

2. Legal basis

The legal basis for this OP is Council Directive 2001/20/EC[1] (Article 15). This Directive (published in 2001) is also known as the Clinical Trials Directive (CTD) and relates to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use. In the UK the CTD was transposed into law by the 'The Medicines for Human use (Clinical Trials) Regulations 2004: SI 2004 No 1031[2]. The UK Regulations took effect on 1 May 2004 and then further amendments.

The Medicines for Human Use (Clinical Trials) Regulations SI 2004/ 1031 as amended outline the responsibilities of the Sponsor to notify the REC and Competent Authority (MHRA in UK) after the conclusion of a trial (UK Regulation No. 27). EU Commission Guidance outlines on posting and publication of result-related information on clinical trials in relation to the implementation of Article 57(2) of Regulation (EC) No 726/2004 and Article 41(2) of Regulation (EC) No 1901/2006

3. Purpose

The scope of this SOP is to inform Investigators and trial staff on the process of end of study notification of GOSH CTIMPs.

4. Definitions

4.1 End of Study Notification

The protocol should have the accurate and appropriate definition of the end of study, e.g. last patient last visit or completion of study follow-up. Any change to this definition is classified as a substantial amendment requiring notification to the NHS Research Ethics Committee (REC), Health Research Authority and to the Medicines and Healthcare products Regulation Agency (MHRA) where applicable. The study database lock and final analysis of the data should be followed after the formal declaration of the end of the study.

If the study is terminating earlier, same procedures should be applied as the end of study notification.

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5. Personnel responsible

It is the responsibility of the CI to complete the appropriate forms and submit these to the Joint R&D office Clinical Trials Manager at the end of the study. Clinical Trials Manager is also responsible for ensuring the end of trial monitoring procedures is in place to ensure data quality and accurate reporting of trial data and final trial analysis.
The Clinical Trials Manager/Coordinator will then forward the information to the REC which gives the favourable opinion of the research and the MHRA as appropriate. It is the CI's responsibility to upload the trial results to the EudraCT website according to the EU commission guidelines.

6. Procedure

6.1 Notification to the sponsor

It is the responsibility of the CI to inform Joint R&D Office Clinical Trials Team when a study has come to an end. The R&D team will inform the CI the deadline for submission of the end of study documents. An electronic copy of the end of study documentation must be sent to the R&D team at the same time as it is sent to the review bodies as below.

6.2 Declaration of the End of a Clinical Trial of an Investigational Medicinal Product to MHRA

A 'Declaration of the end of a Clinical Trial' form should be submitted to the MHRA via CESP within 90 days of the end of the study. Once the declaration of the end of a clinical trial form has been received by the MHRA, only the end of trial study report will be accepted. After this stage it is not possible to submit any further amendments to the trial.

If a trial is terminated

(a) before the date for the conclusion of the trial specified in the protocol for that trial, or

(b) before the event specified in the protocol as the event which indicates the end of the trial

has occurred,

then MHRA and ethics should be notified of the termination of the trial within 15 days of the date of termination.

6.3 Notification to the REC and HRA

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A copy of the end of study notification should be forwarded to Research Ethics Committee and HRA within 90 days of study closure.

6.3 End of trial study report

CI and the trials team are responsible for uploading the end of trial summary results to EudraCT as per the EU commission's guidelines on posting and publication of result-related information. This report should be uploaded within 6 months after the end of the trial, or within 12 months after the end of the trial if justified. CI should always refer to the commission guidelines before submit the report to ethics. CI or the delegate should contact the R&D Clinical Trials Manager to generate the account in the EudraCT portal.

There is no need to submit this clinical trial summary report to the MHRA as well however the CI must send a short confirmatory email to CT.Submission@mhra.gsi.gov.uk once the result-related information has been uploaded to EudraCT, with 'End of trial : result-related information: EudraCT XXXX-XXXXXX-XX' as the subject line. MHRA will not acknowledge this by email or letter. A copy of this email should be filed in the Trial Master File.

A copy of the report from EudraCT should also be submitted to ethics committee.

6.6 Publication and Dissemination

HRA expect the sponsor and the CI to provide Information for participants at the end of the study. This could be an end of study information sheet to participants. If the end of study information sheet builds on the information provided in the original PIS and is in line with the arrangements agreed by the REC as part of their favourable opinion, then the end of study information sheet does not require ethical review by a REC.

A REC review **should be requested** if the information provided to participants at the end of the study or summary results

- is likely to be particularly sensitive or distressing
- contradicts any previous information in the original PIS
- does not follow the original arrangements agreed with the REC

In these circumstances you may need to submit an amendment and a copy of the end of study sheet information sheet to the REC. If in doubt the CI and the trial team should check with the manager of the REC concerned.

Copies of summary results and the end of study information sheets which have been provided to participants should be included in the final report sent to RECs provided to participants should also be included, if they are available at this point in time.

This is a controlled document. Any print-offs of this document will be classed as uncontrolled and colleagues are advised to refer to the Joint GOSH/ICH R&D Office webpage for the latest version.

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There is an expectation that clinical study data be published including a summary of results on a publically accessible register. IRAS ID and details of funder should be acknowledged and included in the summary to ensure transparency of the conduct of the trial.

6.7 Archiving

Following submission of the final study report, all of the study-related and essential documents must be archived following the SOP GOSH/ICH/05/RG17 for Archiving Clinical Research Documents. CI should contact the R&D Office clinical trials team to arrange the archiving of the Trial Master File and at each site it is the PI's responsibility to contact the R&D team to arrange the archiving of their Site File.

7. Associated documents and SOPs*

Document Name	File Path	Author
SOP for Archiving Research Documentation GOSH/ICH/05/RG17	**R&D Folders**	**Dr Vanshree Patel**

8. Recommendations

Not Applicable

9. References

Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products. Official Journal of the European Communities, 9 April 2005; L91/13-19

DIRECTIVE 2001/20/EC of the European Parliament and of The Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. Official Journal of the European Communities, 1 May 2001; L121/34-44

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ICH Harmonised Tripartite Guideline for GCP: adopted in Europe by CPMP in 1996 and published as CPMP/ICH/135/95/Step 5 in Eudralex: The Rules Governing Medicinal Products in the European Union: Volume 3-Guidelines (3CC1A).

Statutory Instrument 2004 No. 1031. The Medicines for Human Use (Clinical Trials) Regulations 2004 The Stationary Office Limited. ISBN 0110490487

Statutory Instrument 2006 No. 1928. The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 The Stationary Office Limited. ISBN 0110748611

10. Appendices

*all these documents are available electronically

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