UNIVERSITY OF ABERDEEN

NHS Grampian

Standard Operating Procedure: Study Closure (Including Procedure for Sudden Closure or Suspension of a Trial)

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1.00	New Document	24/06/2011
1.01	Addition of section 6.1.2. Minor corrections of spelling mistake	22/08/2011

1 PURPOSE / INTRODUCTION

1.1.1 The purpose of this Standard Operating Procedure (SOP) is to describe the procedure for formally closing a clinical trial, including sudden closure or suspension of a trial, for trials sponsored or co-sponsored by University of Aberdeen (UoA) and / or NHS Grampian (NHSG).

1.1.2 The Medicines for Human Use (Clinical Trial) Regulations (2004) and the National Research Ethics Service (NRES) state that for all Clinical Trials of Investigational Medicinal Products (CTIMPs) and for all other clinical trials (non-CTIMPs), written notification of the end of study should be sent to the Medicines and Healthcare products Regulatory Agency (MHRA) as appropriate and the Research Ethics Committee (REC) which gave a favourable opinion of the research); within 90 days of the end of project, or within 15 days of the actual end date if the project is terminated early.

2 SCOPE

2.1.1 This SOP applies to Chief Investigators (CI) of clinical trials sponsored or co-sponsored by the UoA and / or NHSG, and also all staff members of the UoA and / or NHSG who manage, coordinate or advise on clinical trials sponsored by UoA and / or NHSG.

2.1.2 This SOP applies to both CTIMP and non-CTIMP studies.

3 ASSOCIATED DOCUMENTS

UoA-NHSG-SOP-021 - Archiving Clinical Research Data

[1] Declaration of End of Trial Form (CTIMP):
http://ec.europa.eu/health/files/eudralex/vol-10/declaration_end_trial_form.doc

[2] Declaration of end of study (non-CTIMP):
http://www.nres.npsa.nhs.uk/applications/after-ethical-review/endofproject/#Allotherresearch

4 REFERENCES

The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI-1031)
http://www.opsi.gov.uk/si/si2004/20041031.htm
It is assumed that by referencing the principle regulations, all subsequent amendments made to the principle regulations are included in this citation

Medical Research Council Clinical Trials Tool Kit:
http://www.ct-toolkit.ac.uk/route_maps/stations.cfm?current_station_id=327&view_type=map

4.1 **Abbreviations:**

CI	Chief Investigator
CTIMP	Clinical Trial of Investigational Medicinal Product
MHRA	Medicines and Heathcare product Regulatory Agency
NHSG	NHS Grampian
NRES	National Research Ethics Service
R&D	Research and Development
REC	Research Ethics Committee
SOP	Standard Operating Procedure
UoA	University of Aberdeen

5 RESPONSIBILITIES

5.1.1 For clinical trials sponsored or co-sponsored by the UoA and / or NHSG, the responsibility for performing some of the trial closure activities, will be delegated to the CI by the Sponsor. The delegation of responsibility will be agreed before the trial begins and will be documented in the sponsorship / site agreements.

5.1.2 The CI, acting on behalf of the Sponsor, may in turn delegate the responsibility for performing all trial closure activities to a member of the research team. This should be documented in the trial delegation log.

5.1.3 The CI, or delegated member of staff, must notify the appropriate bodies (Sponsor, MHRA, NHS Research and Development (R&D) and REC) of the end of the study as defined in the trial protocol.

5.1.4 It is good practice for the research team to ensure all participants involved in the clinical trial are notified when their participation in the trial is complete.

6 PROCEDURE

6.1.1 The definition of the trial closure should be agreed before the trial begins and should be clearly defined in the trial protocol. In most cases, trial closure will be defined as the date of the last visit of the last participant or the completion of any follow-up monitoring and data collection as described in the trial protocol. If there is any change to this definition, it is the responsibility of the CI to notify this as a substantial amendment.

6.1.2 For all CTIMPs sponsored or co-sponsored by UoA and / or NHSG, a trial closeout visit will be conducted by the NHSG Research Monitor. The CI should contact R&D prior to the scheduled end of the trial or as soon as possible if the trial has been terminated early in order to arrange a suitable time for the closeout visit.

6.1.3 Although undertaken as an ongoing process, it is essential that all original records (e.g. questionnaires, tapes of interviews, trial authorisations such as ethics and R&D approvals) are checked for anonymity (where appropriate) and completeness. Any outstanding errors and inconsistencies should be resolved. It is essential that

the trial master file, and the final database on which the analysis and publication are based, are complete and properly labelled ready for archive.

6.1.4 Final analysis of the data and report writing is normally considered to occur after formal declaration of trial closure.

6.2 Scheduled Closure: End of Trial Notification for CTIMPs

6.2.1 For CTIMPs, it is the responsibility of the CI (or delegate) to complete a 'Declaration of End of Trial form [1] when the trial ends. For multi-centre CTIMPs, the end of trial is considered to be when the trial has ended in all participating centres, in all countries within and outside the European Union (EU).

6.2.2 The 'Declaration of End of Trial form must be sent to the MHRA, REC and Sponsor within 90 days of the trial ending (date as defined in the study protocol).

6.2.3 If the CI decides not to commence a CTIMP after it has been formally approved by the MHRA, they (or their delegate) must notify the MHRA, REC and Sponsor within 15 days of the decision not to commence the trial. The local NHS R&D Office(s) should also be informed if R&D Management Permission had been granted.

6.3 Scheduled Closure: End of Trial Notification for Non-CTIMPs

6.3.1 For non-CTIMPS, the CI (or delegate) must complete a 'Declaration of end of study' form' [2] when the trial ends.

6.3.2 The 'Declaration of end of study' form must be submitted to the REC and Sponsor within 90 days of the ending. The local NHS R&D Office(s) should also be informed when the trial has ended.

6.4 Sudden Closure or Early Termination of Trial

6.4.1 It is important that the plan for scheduled termination of the trial is worked out at the beginning of the trial, since any trial can be terminated "early" at any point after that. This may be due to safety issues, and in such a case, when participants are still being treated.

6.4.2 Immediate action must be taken by the CI to inform both Principal Investigators and participants of the closure.

6.4.3 For CTIMPs that are terminated early, the CI must notify the MHRA, REC and Sponsor within 15 days, by completing a 'Declaration of End of Trial form. The local NHS R&D Office(s) should also be informed that the trial has ended.

6.4.4 For non CTIMPs that are terminated early, the CI must notify the REC and Sponsor within 15 days by completing the "Declaration of end of study' form. The local R&D Office(s) should also be informed when the trial has ended.

6.4.5 In each case the CI must clearly explain within the report, the reasons for terminating the trial early.

6.5 Final Reports and Other Study Closure Activities

6.5.1 Many funding bodies will require a final report to be submitted upon completion of the trial. The format and deadline for these reports will differ depending on the funder, and the CI is responsible for ensuring that they complete these reports accurately.

6.5.2 A summary of the final report on the research may be enclosed with the end of study declaration, or can be sent to the REC and Sponsor subsequently – but it must be sent within 12 months of the end of the trial. It is the responsibility of the CI to submit these summaries.

6.5.3 For CTIMPs, it is a regulatory requirement to summit an end of trial final report to the MHRA within 12 months of the end of the trial.

6.5.4 It is the responsibility of the CI to ensure that the appropriate 'Declarations of End of Trial form' or 'Declaration of the end of study form', together with the final report, is filed appropriately with all the essential research study documentation (as defined in the trial protocol) ready for archiving (refer to SOP: UoA-NHSG-SOP-021 for further guidance).