CLINICAL GOVERNANCE - STANDARD OPERATING PROCEDURE

CLINICAL TRIAL / STUDY CLOSURE

CG-QMS SOP CG14

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Approved by: Signature:	UREC See original

Version History	**Reason for change**

NOTE: All SOPs are subject to regular review.

Please ensure that the version of this SOP is the most up-to-date.

OUT OF DATE DOCUMENTS MUST NOT BE USED AND HARD COPIES SHOULD BE DESTROYED

1. PURPOSE

To outline the process for closing a clinical trial or clinical study and notifying the relevant ethics committee and regulatory body where applicable.

2. SCOPE

This SOP applies to all UoL sponsored clinical research or where LinCTU (Lincoln Clinical Trials Unit) are providing trial management support.

3. BACKGROUND

3.1 The Chief Investigator has overall responsibility for ensuring that all trial closure procedures have been followed and that the relevant notifications have been made.

3.2 A declaration of the declaration of end of study must be sent to the relevant ethics committee and regulatory authority (where appropriate) within 90 days of the (global) end of the trial and within 15 days of the (global) premature end of the trial.

3.3 The conclusion of the research is defined as the final date or event* specified in the protocol, not the completion of data analysis or publication of the results. *Often the conclusion of the research is specified as the last follow-up of the last recruited study/trial participant.

3.4 If the research is terminated early, the Chief Investigator should notify the relevant ethics committee and/or regulatory authority (where appropriate) within 15 days of the date of termination. An explanation of the reasons for the early termination should be given.

Lincoln Clinical Trials Unit (LinCTU)

3.5 Lincoln Clinical Trials Unit (LinCTU) may support the Chief Investigator in completing a clinical trial or clinical study in accordance with the agreed terms and conditions of a signed service level agreement (SLA).

4. CROSS REFERENCES

4.1 CG-QMS SOP CG15 Archiving (Clinical data)

5. PROCEDURE

DECISION TO CLOSE A CLINICAL TRIAL / CLINICAL STUDY

The Chief Investigator or delegated nominee / LinCTU staff shall:

5.1 Inform all participating sites of the impending trial closure, outlining the trial specific processes to be followed for closure.

5.2 Make clear that no more participants are enrolled; that all data collection must be up to date and submitted; that all trial supplies must be accounted for and returned where applicable; and that the trial data and paperwork be appropriately archived.

NOTIFICATION OF CLOSURE TO HRA / NHS REC

The Chief Investigator or delegated nominee / LinCTU staff shall:

5.3 Complete Declaration of the end of a Study Form

5.4 Submit completed form to the REC within 90 days of its conclusion.

5.5 If the research is terminated early, the Chief Investigator should notify the REC within 15 days of the date of termination. An explanation of the reasons for the early termination should be given.

5.6 Reports of conclusion or early termination should be submitted in the form prescribed by the HRA and published on the website.

5.7 Where a project has HRA Approval and has been reviewed by a REC you need only inform the REC when your study has ended. Where a project has HRA Approval and was not reviewed by an NHS REC, you will need to tell HRA when the project has ended.

5.8 If you have an application with the Confidentiality Advisory Group, when your study is completed you should notify the Confidentiality Advice Team as soon as possible in writing.

NOTIFICATION OF CLOSURE TO UoL LEAS (University of Lincoln Ethics Application System)

The Chief Investigator or delegated nominee / LinCTU staff shall:

5.9 Complete the End of Study Declaration in LEAS within 90 days of its conclusion.

5.10 If the research is terminated early, the Chief Investigator should notify the REC within 15 days of the date of termination. An explanation of the reasons for the early termination should be given.

NOTIFICATION OF CLOSURE OF A CTIMP/DEVICE STUDY (CTA APPROVAL) TO MHRA

The Chief Investigator or delegated nominee / LinCTU staff shall:

5.11 Complete A 'Declaration of the end of a Clinical Trial' form (include a brief explanation of the reasons for ending the trial, particularly where the trial has been terminated early) within 90 days of the trial conclusion.

5.12 Submit the form using MHRA Submissions https://icsrsubmissions.mhra.gov.uk/login via the Human Medicines Tile. Please select 'Clinical Trial' as the Regulatory Activity and 'CT –EOT' from the Regulatory sub activity dropdown list.

a. Note: Any trial activities (such as follow-ups, visits) must be completed before the submission of the global end of trial declaration form.

b. It is not possible to submit amendments to the trial or the Development Safety Update Reports (DSUR) once the declaration of the global end of the trial form has been received by the MHRA. If the end of trial declaration has been received within a reporting period, or within 60 days following the data lock point, the corresponding DSUR will not be required.

FINAL REPORT

5.13 A summary of the final report on the research should be provided to the sponsor, REC and any participating sites (where applicable) within 12 months of the conclusion of the study in accordance with 5.18-5.25. This should include information on whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research including any feedback to participants.

REPORTING RESULTS

5.14 Other than research for educational purposes and early phase trials, the findings, whether positive or negative, should be made accessible, with adequate consent and privacy safeguards, in a timely manner after they have finished.

5.15 Where appropriate, information about the findings of the research should be made available, in a suitable format and timely manner, to those who took part in it, unless otherwise justified.

CLINICAL TRIAL SUMMARY RESULTS

5.16 The time frame for publishing the summary of results is within 6 months of the end of trial for paediatric clinical trials and within one year of the end of trial for non-paediatric clinical trials.

5.17 You should publish your summary results within these timeframes in the public register (or registers) where you have registered your clinical trial.

Note: You do not need to submit this clinical trial summary report to the MHRA as well however, you must send a short confirmatory email to CT.Submission@mhra.gov.uk. The subject line of the email notification must state 'End of trial: result-related information: EudraCT XXXX-XXXXXX-XX' once the result-related information has been uploaded to the public register.

NOTIFYING THE SPONSOR

5.18 Send a copy of any relevant Declaration of End of Study forms and any correspondence to the study sponsor.

5.19 A member of the research governance team will complete the study on the sponsors study database.

NOTIFYING PARTICIPATING SITES

5.20 Inform all participating sites that the study is closed. Send a copy of any relevant Declaration of End of Study forms to R&D sites, so that the site may be formally closed.

5.21 Make clear that no more participants are enrolled; that all data collection must be up to date and submitted; that all trial supplies must be accounted for and returned where applicable; and that the trial data and paperwork be appropriately archived.

5.22 ARCHIVING

5.23 The Chief Investigator or delegated nominee / LinCTU staff shall:

5.24 Archive all clinical trial / study data in accordance SOP CG15 Archiving (Clinical data)

5.25 For participating sites, the local Principal Investigator is responsible for the return of all trial supplies and data from their site to the Chief Investigator in accordance with the protocol and SOP CG15 Archiving (Clinical data) and in accordance with any host site archiving requirements.

6. FLOW CHART

None required.