

Title: Research project closure	
Effective Date: 1-6-22	Review Date: 1-6-25
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Document History

Version	Description of update	Date Effective
1	Change of number for Q-Pulse Addition of R&D at 3.17	2-10-15
2	Change of title and reformatted Addition of Medical device Trials at 1.2, 3.7 and 3.17	1-4-17
3	Text reordered at 3 and clarification of process at 3.10 Updated to include Funder at 3.19-3.21 Medical Device Clinical Investigation added at 3.20 Heading changed at 3.24 and abbreviations added at 4	1-8-20
4	Reference to agreements in place at early closure at 3.23	1-6-22

1. Scope

1.1 This SOP applies to Chief Investigators (CI) and all staff of University of Aberdeen (UoA) and/or NHS Grampian (NHSG), who manage, coordinate or advise on research projects sponsored or co-sponsored by (UoA) and/or (NHSG).


1.2 This SOP applies to all research projects; Medical Device Clinical Investigations (MDCIs), Clinical Trials of Investigational Medicinal Products (CTIMPs) and all other research studies (non-CTIMPs) that are sponsored or co-sponsored by UoA and/or NHSG.


2. Responsibilities

Chief Investigator (CI) Ensure 'end of study/trial' is clearly defined in the protocol and inform appropriate bodies of the end of study, suspension or termination.

Sponsor To determine if a close-out monitoring visit is required


3. Procedure


3.1  The definition of project closure shall be agreed before the research project begins and be clearly defined in the research protocol (see SOP-QA-3 – Protocol Guidance for High Risk Trials and CTIMPs). In most cases, project closure shall be defined as the date of the last visit of the last participant or the completion of any follow-up monitoring and data collection. If there is any change to this definition, this is considered a substantial amendment (see SOP-QA-19 – Amendments).


3.2  For research projects sponsored or co-sponsored by the UoA and/or NHSG, the responsibility for performing some of the project closure activities, shall be delegated to the CI by the Sponsor.


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3.3  The CI, acting on behalf of the Sponsor, may in turn delegate the responsibility for performing specific project closure activities to a senior member of the research team.

3.4  The CI, or delegated member of staff, must notify the appropriate bodies (eg Sponsor, Research Funder, REC, R&D and MHRA) of the end of the study, as defined in the research protocol.

3.5  The CI shall inform Sponsor immediately if a study is suspended due to urgent safety issues.

3.6  The CI shall inform and seek approval from the relevant project oversight committees, as appropriate (eg Project Management Group (PMG), Trial Steering Committee (TSC; which involves representation from the Sponsor), Data Monitoring Committee (DMC)), prior to terminating a study.


3.7 For all CTIMPs and MDCIs sponsored or co-sponsored by UoA and/or NHSG, a trial close-out visit shall be conducted by the NHSG Research Monitor(s) at the Grampian site (see SOP-QA-28 – Monitoring).  The CI shall contact R&D prior to the scheduled end of the trial, or as soon as possible if the trial has been terminated early, to arrange a suitable time for the close-out visit.

3.8 Final analysis of the data and report writing is normally considered to occur after formal declaration of research project closure, but before the project is archived.

Scheduled closure - CTIMPs


3.9 It is the responsibility of the CI (or delegate) to complete a 'Declaration of the End of Trial' form when the CTIMP ends: <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/> For multi-centre CTIMPs, the end of trial is considered to be when the trial has ended in all participating centres and countries, within and outside the European Union.


3.10 The 'Declaration of the End of Trial' form must be sent to the Sponsor, MHRA and REC within **90 days** of the trial ending (date as defined in the study protocol). You must submit your end of trial declarations via the Common European Submission Portal ([CESP](https://www.cepportal.eu/)). A copy should also be sent to the local R&D Office(s) if R&D Management has been granted (or is pending).

3.11  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 Sponsor, MHRA and REC within 15 days of the decision not to commence the trial. The local R&D Office(s) must also be informed if R&D Management Permission had been granted (or is pending).

Scheduled closure – non-CTIMPs

3.12 For non-CTIMPs, the CI (or delegate) must complete a 'Declaration of the End of a Study' form when the study ends: <http://www.hra.nhs.uk/resources/during-and-after-your-study/end-of-study-notification-studies-other-than-clinical-trials-of-investigational-medicinal-products/>


3.13  The 'Declaration of the End of a Study' form must be submitted to the Sponsor and REC within **90 days** of ending. A copy should also be sent to the local R&D Office(s) if R&D Management Permission has been granted (or is pending).


3.14  If the CI decides not to commence a non-CTIMP after REC approval they (or their delegate) must notify the Sponsor and REC of the decision not to commence the study. The local R&D Office(s) must also be informed if R&D Management Permission had been granted (or is pending).


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Research project suspension

3.15  Consideration should be in place for possible suspension of the research project, since any research project can be suspended at any point. Project suspension may for example be due to safety issues eg an Urgent Safety Measure or a Serious Breach (see SOP-QA-25 – Deviations and Breaches) and in such cases, prior to completion of recruitment. If the CI suspends a study on urgent safety grounds, Sponsor must be informed immediately.


3.16  The CI must formally notify all relevant review bodies of the temporary suspension including Research Ethics Committee (REC), R&D and MHRA if a CTIMP or MDCI, within **15 days**. The notification to REC should be made as a substantial amendment using the notification of amendment form, clearly explaining what has been stopped and the reasons for the suspension. For further details see: <https://www.hra.nhs.uk/approvals-amendments/amending-approval/>


3.17  The CI must also contact the project oversight committees (PMG, TSC and DMC, as appropriate) to discuss the temporary suspension with them.


3.18 A decision by the research project oversight committees should then be made as to whether the reason for the temporary suspension can be resolved or not:


- If it can be **resolved**, and the research can restart, the CI should obtain permission from Sponsor and then make the request to REC, and MHRA if a CTIMP, as a substantial amendment using the notification of amendment form, providing evidence that it is safe to restart, or
- If it can't be resolved, then **early termination** is required, in which case the procedures for early termination should be followed as described below.


Early termination of a research project

3.19  It is important that the plan for termination of a research project is worked out early in the study (ideally before the first randomisation), since any study can be terminated at any point after that. There are a number of reasons why a research project may terminate early prior to the protocol defined recruitment target or prior to follow-up being completed. Before a study can terminate, the CI must seek approval from the project oversight committees (PMG, TSC and DMC, as appropriate) (see SOP-QA-17 – Project committees) and then formally inform Sponsor and Funder.

3.20  Once approval to terminate a CTIMP or a MDCI has been obtained from the project oversight committees (as appropriate), Sponsor and Funder, the CI must formally notify the MHRA and REC within **15 days**, by completing a 'Declaration of the End of Trial form' (see 3.8). The CI must clearly explain the reasons for terminating the project early. A copy should also be sent to the local R&D Office(s) if R&D Management has been granted (or is pending).

3.21  Once approval to terminate a non-CTIMP has been obtained from the project oversight committees (as appropriate), Sponsor and Funder, the CI must formally notify the REC within **15 days** by completing the 'Declaration of the End of a Study form' (see 3.12). The CI must clearly explain within the form the reasons for terminating the project early. A copy should also be sent to the local R&D Office(s) if R&D Management has been granted (or is pending).

3.22  If the study is still recruiting, the CI (or delegate) must ensure that no further participants are recruited or randomised to the research project.


3.23  If it is agreed the research project is to be terminated early, the CI must inform all the appropriate parties (eg Principal Investigator's (PIs), pharmacy, participants as appropriate) of this

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decision. Consideration should also be given to any agreements in place for the trial, for example supply agreements and these should be discussed with Research and Innovation (R&I) before contact is made with the third party. The plan for close-out should then be followed.

Additional research project closure activities (scheduled closure and early termination)

3.24  At the end of the research project, the CI is expected to fulfil commitments made to research participants in terms of care after research and providing information about the outcomes of the research project, as detailed in the protocol.

3.25 Although undertaken as an ongoing process, it is essential that all original records (eg questionnaires, tapes of interviews, research project authorisations such as ethics and R&D permissions) are checked for anonymity (where appropriate) and completeness. Any outstanding errors and inconsistencies must be resolved and the TMF, and final database, on which the analysis and publication is based, are complete and properly labelled ready for archiving.

3.26  At the end of the research project, the CI is responsible for various final reporting procedures including reporting to Funder(s), Sponsor(s), REC and MHRA, if applicable, as well as publishing and disseminating the research project results (see SOP-QA-33 – Research Project Publication and Dissemination).

3.27  The CI shall ensure that the appropriate 'Declaration of the End of a Trial' form or 'Declaration of the End of a Study' form, together with the final report, is filed appropriately within the TMF, ready for archiving (see SOP-QA-32 – Archiving).


4. Abbreviations and definitions

CESP	Common European Submission Portal
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
DMC	Data Monitoring Committee
MDCI	Medical Device Clinical Investigation
MHRA	Medicines and Healthcare products Regulatory Agency
PMG	Project Management Group
R&D	Research and Development (NHS)
REC	Research Ethics Committee
TMF	Trial Master File
TSC	Trial Steering Committee

5. Related documentation and references

SOP-QA-3	Protocol guidance for high risk trial and CTIMPs
SOP-QA-17	Project committees
SOP-QA-19	Amendments
SOP-QA-20	Data management for clinical trials
SOP-QA-22	Adverse Events in CTIMPs
SOP-QA-25	Deviations and Breaches
SOP-QA-28	Monitoring
SOP-QA-32	Archiving
SOP-QA-33	Research project publication and dissemination
SOP-QA-39	Adverse Events in Medical Device Clinical Investigations

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