SOP-QA-31 V6

Title: Research project closure

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Document History

Version	Description of update	Date Effective
5	Update to the reporting process for CTIMPs 3.10 – 3.12 Addition of a new section to define the process specifically for MDCIs	21-05-25
6	Updated terminology at 3.1 and 3.23 Reference to clinical trial suspension timelines at 3.5 Clarification of trial summary publication deadline 3.8 Reference to CTA lapsing if no recruitment at 3.14	28-04-26

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

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

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

3.4 ⚠ The CI, or delegate, 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 (see SOP-QA-4**2** – Urgent Safety measures**)**. Notification of a temporary halt shall follow usual timelines for reporting an Urgent Safety Measure (see regulation 30 of the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025.

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/co-sponsored by UoA and/or NHSG, a study close-out visit shall be conducted by the NHSG Research Monitor(s) at the Grampian location/site (see SOP-QA-28 – Monitoring). ! The CI shall contact QA prior to the scheduled end of the study, or as soon as possible if the study is terminated early, to arrange a suitable time.

3.8 Final analysis of the data and report writing is normally considered to occur after formal declaration of the end of study, but before the project is archived.
⚠ A trial summary must be published within 12 months of conclusion of the trial and a summary of results must be offered to all participants and/or relevant persons in a manner that is understandable to laypersons.

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 or MDCIs, 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 IRAS and/or research protocol). Please refer to www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues for details on submitting the end of trial declaration, which is completed via the MHRA Portal. 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 For trials submitted through combined review, complete and submit the end of trial form in the Integrated Research Application System (IRAS) which will automatically submit the notification to the REC and MHRA.

3.12 A summary of the results must be published on the public registry (or registers) where the trial is registered, and offered to participants, within 12 months.

3.13 ⚠ For CTIMPS that were previously registered on EudraCT, the clinical trial summary results must also be reported to EudraCT within six or 12 months depending on the type of trial. The MHRA must be emailed (via CT.Submission@mhra.gov.uk) to inform them that the trial results have been posted to EudraCT (see www.gov.uk/guidance/ clinicaltrials-for-medicines-manage-your-authorisation-report-safety-issues#end-of-trial for details).

3.14 ⚠ 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).

❗ Clinical Trial Approval lapses after 24 months if the trial has not recruited.

Scheduled closure –MDCIs

3.15 For MDCIs, it is the responsibility of the CI (or delegate) to complete a 'Declaration of the End of Trial' form when the study ends: https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/.

3.16 The 'Declaration of the End of Trial' form must be sent to the Sponsor and REC within **90 days** of the trial ending (date as defined in the IRAS and/or research protocol). A copy of the end of study report should also be emailed to MHRA via CI-applications@mhra.gov.uk, and sent to the local R&D Office(s) if R&D Management has been granted (or is pending).

Scheduled closure – non-CTIMPs

3.17 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/

3.18 ⚠ 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).

3.19 ⚠ 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).

Research project suspension

3.20 ❗ 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 (see SOP-QA-42 – Urgent Safety measures) or a Serious Breach (see SOP-QA-43 – Suspected Serious Breaches), because of a product recall or a major external event such as a pandemic, and in such cases, prior to completion of recruitment. If the CI suspends a study on urgent safety grounds, Sponsor must be informed immediately.

3.21 ⚠ 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 modification using the notification of modification form (see SOP-QA-19 – Modifications), clearly explaining what has been halted (eg stopping recruitment and/or interrupting treatment of participants already included) and the reasons for the suspension. For further details see: https://www.hra.nhs.uk/approvals-amendments/amending-approval/

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

3.23 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 modification using the notification of modification form, providing evidence that it is safe to restart, or
- If it cannot 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

3.24 On occasion, a trial may be terminated early and a plan for termination should be prepared early in the study (ideally before the first randomisation). 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 (for example, futility, safety, funding, etc). 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.

3.25 If it is agreed the research project is to be terminated early, the CI must inform all the appropriate parties (eg Principal Investigators (PIs), pharmacy, participants as appropriate) of this decision. Consideration should also be given to any agreements in place for the trial, for example supply agreements and these should be discussed with the sponsor's contract team before contact is made with the third party. The plan for close-out should then be followed.

3.26 **CTMPs and MDCIs:** 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**, or **24 hours** if the decision was taken on safety grounds, by completing a 'Declaration of the End of Trial form' (see 3.9). 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).

3.27 **non-CTIMPs:** 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).

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

Additional research project end of study activities (scheduled closure and early termination)

3.29 At the end of the research project, the CI is expected to fulfil commitments made to research participants in terms of thanking them for their contribution and providing information about the outcomes of the research project, as detailed in the protocol.

3.30 Although undertaken as an ongoing process, it is essential that all original records (eg questionnaires, recordings 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 Trial Master File (TMF), and

final database, on which the analysis and publication is based, are complete and properly labelled ready for archiving.

3.31 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). The final trial report to the REC, should be completed and submitted using the following online form: https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/final-report-form/ within 12 months of end of the trial.

3.32 For CTIMPs, the summary of results must be published on the public registry, and offered to participants, within 12 months after the conclusion of the trial. For CTIMPS that were previously registered on EudraCT, the clinical trial summary results will also need to be reported to EudraCT within six or 12 months depending on the type of trial

3.33 At the end of the research project, depending on the funding, the CI and UoA colleagues in Research Financial Services, should ensure that any end of trial financial procedures have been considered and completed.

3.34 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 (see SOP-QA-7 - Trial Master File), 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 clinical trials and CTIMPs
SOP-QA-7	Trial Master File
SOP-QA-17	Project committees
SOP-QA-19	Modifications
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
SOP-QA-42	Urgent Safety Measures
SOP-QA-43	Suspected Serious Breach