Title: Research project closure

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 Trials, 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 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 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 and shall be documented in the Sponsorship delegation log.

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

3.3 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.

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

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

3.6 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).

3.7 For all CTIMPs and Medical Device Trials 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 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, in all countries within and outside the European Union (EU).

3.10 The ‘Declaration of 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). A copy should also be sent to the local R&D Office(s) if R&D Management has been granted (or is pending).

In order to ensure proof of delivery of this form to the MHRA (as it’s receipt is not always acknowledged) a signed for delivery service should be used and copies of the delivery request and proof of delivery should be retained in the TMF. A copy of the safe receipt and/or courier request/waybill should also be retained as evidence that the form was actually received.

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 End of Study’ form when the non-CTIMP 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 End of Study’ form must be submitted to the Sponsor and REC within 90 days of the ending. A copy should also be sent to the local R&D Office(s) if R&D Management 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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Key to symbols:  ⚠ = Warning  ⚠ = Important point to note
Research project suspension

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

3.16  🔴 The CI must also inform and arrange to discuss with the Project Management Group (PMG), Trial Steering Committee (TSC; which involves representation from the Sponsor), and the Data Monitoring Committee (DMC), as appropriate (see SOP-QA-17 – Project committees).

3.17  🔴 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 Medical Device Trial, 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/](https://www.hra.nhs.uk/approvals-amendments/amending-approval/)

3.18 A decision by the research project oversight committees (PMG, TSC and DMC, as appropriate) should then be made as to whether the reason for the temporary suspension can be:

- **resolved** and the research project can restart, in which case 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
- **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 ‘early’ 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 follow-up being completed. Before a study can terminate the CI must seek approval from the Project Management Group (PMG), Trial Steering Committee (TSC; which involves representation from the Sponsor), and the Data Monitoring Committee (DMC), as appropriate (see SOP-QA-17 – Project committees) and then formally inform Sponsor.

3.20  🔴 Once approval to terminate a CTIMP has been obtained from the Sponsor, TSC and any other study committees as appropriate the CI must formally notify the MHRA and REC within **15 days**, by completing a ‘Declaration of 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 Sponsor, TSC and any other study committees as appropriate the CI must formally notify the REC within 15 days by completing the ‘Declaration of End of 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 decision. The plan for close-out should then be followed.

**Additional research project closure activities**

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.

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. The Trial Master File (TMF), and the 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 shall be responsible for various final reporting procedures including reporting to the 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 End of Trial form’ or ‘Declaration of the End of 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

- **DMC** Data Monitoring Committee
- **HRA** Health Research Authority
- **MHRA** Medicines and Healthcare products Regulatory Authority
- **PMG** Project Management Group
- **REC** Research Ethics Committee
- **TSC** Trial Steering Committee

### 5. Related documentation and references

- SOP-QA-3 Protocol guidance for high risk trial and CTIMPs
- SOP-QA-7 Trial Master file
- 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 Trials

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