BU Bournemouth University

BU RDS SOP 015 V1

Title: Study Closure	
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1. Scope

1.1 This Standard Operating Procedure (SOP) applies to all Chief Investigators (CI)/Researchers and all staff at Bournemouth University (BU) who manage, coordinate or advise on BU sponsored projects.

1.2 This SOP applies to all categories of research projects: Clinical Trials of Investigational Medicinal Products (CTIMPs), Medical Device Trials, and all non-CTIMPs, that BU sponsors or co-sponsors.

2. Responsibilities

The *Chief Investigator (CI) /Researcher* should ensure that the 'end of study/trial' is clearly defined in the protocol, and is responsible for ensuring that all appropriate bodies are notified about the end of the study, suspension or termination.

The *Sponsor* is responsible for assessing whether a close-out monitoring visit is required.

3. Procedure

3.1 The Sponsor shall delegate some project closure duties to the CI/Researcher, and this shall be documented in the Trial Master File (TMF).

3.2 The CI, on behalf of the Sponsor may then delegate certain project closure duties to members of the research team. The CI will be responsible for ensuring that these duties are carried out.

3.3 The CI/Researcher should notify the appropriate bodies (Sponsor, Funder, Research Ethics Committee [REC], Research & Development [R&D], and the Medicine and Healthcare products Regulatory Agency [MHRA] where appropriate and relevant to the research) of the end of the study, as outlined in the study protocol.

3.4 The CI must inform the Sponsor immediately should the study be suspended due to an urgent safety issue.

3.5 The CI must inform and seek approval from the Sponsor prior to terminating a study.

3.6 The study closure date should be defined and agreed before the study begins, and clearly identified in the protocol. Ordinarily, the study closure date is defined as the last visit

of the last study participant, or the completion of any follow-up monitoring and data collection. If the CI/Researcher decides to change the definition of study closure, then they should submit a Substantial Amendment (see BU RDS SOP 002).

3.7 For all CTIMPs and Medical Device Trials that are sponsored or co-sponsored by BU, the Clinical Governance Advisor (CGA) will conduct a trial close-out visit at the site(s) involved. The CI/Researcher should contact their NHS R&D contact(s) prior to the scheduled end of trial, or as soon as possible if the trial is ended early, to arrange a suitable time for conducting the close-out visit.

3.8 Final data analysis and report writing will normally occur after formal declaration of the study closure, but before the study is archived.

CTIMPs – Scheduled Closure

3.9 When a CTIMP ends, it is the responsibility of the CI or delegate to complete a 'Declaration of End of Trial' form - https://www.hra.nhs.uk/documents/1100/declaration_end_trial_form.doc. For multi-centre CTIMPs, the end of the trial is when it has ended at all participating sites, in all countries.

3.10 The above form must be sent by the CI or delegate, to the Sponsor, MHRA and REC within 90 days of the trial end date (as defined in the study protocol). They should also send a copy to the NHS R&D offices hosting/interested in hosting the study.

The CI or delegate should submit the form to the MHRA using the Common European Submission Portal - http://cesp.hma.eu/Home. File confirmation of this submission in the TMF.

3.11 If the CI decides that a CTIMP should not go ahead after it has received formal approval by the MHRA, then they or their delegate must notify the Sponsor, MHRA and REC within 15 days of the decision. If NHS R&D office(s) have granted or were planning to grant Trust agreement, they must also be informed.

Non-CTIMPs – Scheduled Closure

3.12 When a non-CTIMP ends, it is the responsibility of the CI/Researcher to complete a 'Declaration of End of Trial' form (different to the form used for CTIMPs) - https://www.hra.nhs.uk/documents/1101/nres-declaration-end-study-form-v1-3.docx.

3.13 The above form must be sent by the CI/Researcher, to the Sponsor and REC within 90 days of the trial end date (as defined in the study protocol). They should also send a copy to the NHS R&D offices hosting/interested in hosting the study.

3.14 If the CI decides that a non-CTIMP should not go ahead after it has received favourable opinion by the REC, then they or their delegate must notify the Sponsor and REC of their decision. The NHS R&D office(s) must also be informed if they have granted or were planning to grant Trust agreement.

3.15 Where a project has Health Research Authority (HRA) Approval and was not reviewed by an NHS REC, the HRA should be notified when the project has ended. Notification can be

sent by email to hra.approval@nhs.net including the study IRAS ID and CI contact information (phone and email).

Suspending Research Projects

3.16 When project planning, it is important to make arrangements for the possible suspension of the research project. Projects may be suspended at any point, for example due to a *serious breach* (see BU RDS SOP 011), or sometimes prior to any recruitment taking place. If the CI decides to suspend the study due to urgent safety issues, then they must inform the Sponsor immediately.

3.17 The CI must formally notify all the relevant bodies of the temporary suspension, as well as the Sponsor and R&D, within 15 days. The notification to the REC should be made as a Substantial Amendment, using the amendment form, and should clearly explain what has been stopped and the reasons for this.

Early Termination of a Research Project

3.18 It is imperative that any plan to terminate a research project earlier than the protocol defined recruitment target or follow-up completion date is decided as early as possible in the study, and before the first randomisation if possible. Early termination must be agreed by the Sponsor, and the CI/Researcher is responsible for seeking this approval.

3.19 Once the Sponsor has given approval for a CTIMP to be terminated, the CI must then notify the MHRA and REC within 15 days by completing the form in section 3.9. In reporting this, the CI must explain the reasons as to why the project has been terminated early. The CI should also send a copy of this form to the NHS R&D Office(s) if they have granted, or were planning to grant Trust agreement.

3.20 Once the Sponsor has given approval for a non-CTIMP to be terminated, the CI/Researcher must then notify the REC within 15 days by completing the form in section 3.9. In reporting this, the CI must explain the reasons as to why the project has been terminated early. The CI should also send a copy of this form to the NHS R&D Office(s) if they have granted, or were planning to grant Trust agreement.

3.21 If the study is still recruiting, then the CI or delegate must ensure that no further participants are recruited or randomised to the study.

3.22 If the study is terminated early, then the CI must inform all the participating sites of the decision, as well as study participants (if appropriate). The plan for close-out should then be followed.

Additional Activities Required

3.23 At the end of the study, the CI/Researcher is expected to fulfil their obligations to research participants with regard to care after research and providing information concerning the outcomes of the study.

3.24 All original records and study authorisations/permissions should be checked for completeness, ensuring that applicable documents anonymised. In carrying out these checks, any errors or inconsistencies must be resolved. The TMF and final database, on

which the analysis and publication are based, must be complete and labelled ready for archive.

3.25 The CI/Researcher is responsible for final reporting procedures including the report to the funder(s), Sponsor, REC and MHRA, and if applicable, they are responsible for the publishing and dissemination of the study results.

3.26 The CI/Researcher will ensure that the '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.

4. Abbreviations and definitions

CGA	Clinical Governance Advisor
CI	Chief Investigator
CTIMPs	Clinical Trial of an Investigational Medicinal Product
IRAS	Integrated Research Application System
MHRA	Medicines and Healthcare products Regulatory Agency
R&D	Research and Development (NHS Research Governance)
REC	Research Ethics Committee
TMF	Trial Master File

5. Related documentation and references

BU RDS SOP 002 - Amendments

BU RDS SOP 011 – Safety Reporting

Common European Submission Portal - http://cesp.hma.eu/Home

CTIMPs - https://www.hra.nhs.uk/documents/1100/declaration_end_trial_form.doc

Non-CTIMPs - https://www.hra.nhs.uk/documents/1101/nres-declaration-end-study-form-v1-3.docx