STANDARD OPERATING PROCEDURE FOR CLOSURE OF CLINICAL RESEARCH STUDIES

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1. PURPOSE

This document describes the procedure used for closure of clinical research studies.

It is the responsibility of all staff using this SOP to ensure they are using the latest version of it. The latest version is available via StaffLink, the R&D SOP tab of the Research, Innovation and Knowledge section of the NHS Fife website (www.nhsfife.org/research) and EDGE (https://www.edge.nhs.uk). For guidance, contact the R&D Department via fife.randd@nhs.scot.

2. APPLICABILITY

This document applies to all clinical research sponsored or co-sponsored by NHS Fife.

- Chief Investigators (CIs) and other research staff, in the investigator team or in support departments, working on studies sponsored or co-sponsored by NHS Fife.

- Principal Investigators (PIs) and other research staff, in the investigator team or in support departments, at sites where multi-site studies sponsored or co-sponsored by the NHS Fife are being run.

- NHS Fife R&D Department staff who manage the sponsorship of studies on behalf NHS Fife.

3. POLICY

3.1 Study close-out is the act of ensuring that all research related activities have been appropriately reconciled. Close-out is integral to the quality of a study and is designed to ensure that all necessary documents are in place should the study data need to be queried or inspected in the future.

3.2 The definition of the end of the study must be provided in the Protocol and any change to this definition must be notified, first to the Sponsor, and subsequently to the REC which gave a favourable opinion of the research as a substantial amendment. The recommended definition of end of study is ‘last participant, last visit’ but this may be changed if appropriate e.g., study database lock (end of data capture).

3.3 Final analysis of the data (following 'lock' of the study database) and report writing is normally considered to occur after the formal declaration of the end of the study.

3.4 The Chief Investigator (CI) site must not be closed until all the participating sites have been closed out.

4. PROCEDURE

4.1 A site must be closed as soon as is practicable to do so. A site may be deemed "closed" once all study-related activities at a particular site are reconciled and/or complete. This includes ensuring:

- All Adverse Events have been followed up to resolution (see R&D SOP 31).
- Investigator and Sponsor files are reviewed and all essential documentation for a particular site are confirmed in the appropriate files, providing a clear audit trail of study conduct at the site.
- All site data is collected, entered, validated and all data queries resolved where feasible. This includes queries resulting from reconciliation of the clinical and safety database.
- All issues from previous study monitoring procedures are resolved and documented.
- All financial matters are resolved and all site payments are complete as agreed and documented in study contracts/agreements/approvals.
- All unused study supplies are returned or destroyed according to study and/or Sponsor requirements.
- Investigator(s) are aware of the study publication policy, as documented in the study protocol and/or study contracts/agreements.
- Investigator(s) are aware of and have implemented relevant ongoing requirements such as site archiving, subsequent audit/inspection procedures and any ongoing reporting requirements.

4.2 End of Study Declaration

4.2.1 It is the responsibility of the Chief Investigator (CI) to notify the Sponsor (via fife.fiferesearchapprovals@nhs.scot) and REC of the end of the study by submitting a Declaration of the End of a Study form.

The Declaration of the End of a Study form can be found at: https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/

4.2.2 The Declaration of the End of a Study form must be submitted by email to the REC that issued the favourable opinion, within 90 days of the end of study (see Section 3.2).

4.2.3 If the study is terminated early, the Declaration of the End of a Study form must be submitted within 15 days of the study end date and must include an explanation of the reasons for early termination.

4.2.4 Where the study is a multi-national study the Declaration refers to the end of study in all participating countries and not just in the UK.

4.2.5 Before submitting the Declaration, the plans that have been approved by the REC for the use of tissue and data collected during the study, providing information to participants, and dissemination of results must be reviewed. If any changes to these are required, consideration must be given to whether a substantial amendment is required, before submitting your End of Study Declaration.

4.2.6 Acknowledgement of the Declaration must be filed in the Study Master File (SMF).

4.3 Study Halt

4.3.1 When the Sponsor or CI halts a study temporarily, the REC must be notified by the CI within 15 days from the date the study is temporarily halted. The notification will be made as a substantial amendment using the IRAS Notification of Substantial Amendment Form. An explanation as to what has been halted and the reasons for the temporary halt must be included.

4.3.2 To restart a study that has been temporarily halted, the CI must make the request to the REC as a substantial amendment using the IRAS Notification of Substantial Amendment Form and must provide evidence that it is appropriate to restart the study.

4.3.3 If the Sponsor decides not to recommence a temporarily halted study, the CI must submit an End of Study Declaration to the REC within 15 days of the decision and include an explanation of the reasons for ending the study.

4.4 Study Does Not Commence

If the Sponsor or CI decides that a study will not commence**,** the CI must notify the REC, explaining the reasons for non-commencement.

4.5 Final Reports

4.5.1 The CI must send an end of study report to the REC and Sponsor (via fife.fiferesearchapprovals@nhs.scot) within 12 months of the end of the study. For multi-national studies the end of study is the end date in all participating countries and not just in the UK.

4.5.2 The report must include, as a minimum, information on whether the study achieved its objectives, the main findings, and arrangements for publication/ dissemination of the research, including any feedback to participants. For further guidance on the format of report writing see the HRA website: http://www.hra.nhs.uk/research-community/end-of-study-and-beyond/notifying-the-end-of-study/.

4.5.3 All correspondence with the REC must be retained in the SMF and Investigator Site File (ISF).

4.6 Study Archiving

Study archiving must be performed in line with R&D SOP35 ensuring that files are retrieved from support departments so that all essential documents relating to a particular study are archived together.

5. ASSOCIATED DOCUMENTS

R&D SOP31 - Identifying, Recording and Reporting Adverse Events for Research Sponsored by NHS Fife.

R&D SOP35 - Archiving.

6. ABBREVIATIONS

CI	Chief Investigator
GCP	Good Clinical Practice
HRA	Health Research Authority
ISF	Investigator Site File
REC	Research Ethics Committee
SOP	Standard Operating Procedure
SMF	Study Master File

7. DOCUMENT HISTORY

Version Number	Edited by (job title)	Effective Date	Details of Revisions Made
1	Julie Aitken R&D Trials Facilitator	06 April 2015	New - Adapted from TASC SOP 16, version 3.0
2	Julie Aitken R&D Trials Facilitator	26 Feb 2019	Reformatted in line with current SOP template. Revised to cover Non-CTIMP studies sponsored by NHS Fife.
3	Julie Aitken R&D Quality & Performance Lead	18 Jul 2022	Details of all end of study checks added. Text refreshed and reformatted for clarity

8. APPROVAL

APPROVED BY	Date
Professor Frances Quirk, Assistant Director Research, Innovation & Knowledge, NHS Fife Signature: 	18 July 2022