

SOP number	51.019	Version	5.0
Title	Sponsor – End of Study Procedures		

Prepared by	Shanice White
Approved by	Melissa Robert
Released by	Jesse Dawson

SOP category	NHS GG&C Sponsor R&I			
Staff category				
Staff Category	R	A	C	I
Systems & Operations Manager		X		
Senior Research Administrator	X			
Research Administrators	X			
Research Information Officer	X			
Innovation Project Manager	X			
Innovation Sponsor Co-Ordinator	X			
Sponsor Research Co-Ordinator	X			
Chief Investigators	X			
Principal Investigators			X	
Research Governance Manager			X	
Sponsor Pharmacy				X
Clinical Trial Monitors				X
Project Managers				X

1. Scope

This procedure applies to NHS Greater Glasgow and Clyde (NHSGGC) Research and Innovation (R&I) staff involved in Sponsor oversight, administration, notification, closure and archiving arrangements for research studies sponsored or co-sponsored by NHSGGC, including CTIMPs, CIMDs and non-CTIMP research studies.

2. Purpose

The purpose of this SOP is to define the process for Sponsor oversight of end-of-study activities, including identifying studies approaching or passing their recorded end date, confirming study status, ensuring required notifications are made to relevant review bodies, ensuring end-of-study documentation is obtained and filed, updating relevant R&I systems and initiating archiving arrangements.

3. Procedures

3.1. End of study reports

A monthly end date report is generated by the informatics team for active and in follow-up studies which are due to pass their study end date within the next 3 months, or have passed their study end date, to ensure the Sponsor team has oversight of study status. The Senior Research Administrator (SRA) will email the Chief Investigator (CI) and Principal Investigator (PI) using Form 51.019A: Project Status Email Template to confirm the current study status.

Upon receipt of confirmation, the SRA will update Scottish Research Database Application (SReDA) accordingly. If no response is received, two further follow up emails will be sent, including the wider study team and, where appropriate, the CI's line manager. Where no response is received after three emails over three months, the matter will be escalated to the Research Governance Manager (RGM) and reported as a non-compliance as per SOP 51.008. The RGM will then contact the CI directly and advise that the study may be closed if a modification to extend is not submitted. The RGM will then confirm to the Sponsor Research Co-ordinator (SRC)/ Innovation Sponsor Co-ordinator (ISC) if the study should proceed to closure.

If the PI/CI wishes to extend the study end date, a modification must be submitted to the SRC for Sponsor review and approval prior to submission to the Research Ethics Committee (REC), Medicines and Healthcare products Regulatory Agency (MHRA), or any other relevant regulatory or review body as per SOP 51.021.

3.2. Non-CTIMPs

3.2.1. End of Study Declaration – Studies Submitted to a REC

The end of study will be defined within the approved study protocol. Relevant review bodies must be notified of the end of study.

The CI or Project Manager (PM) is responsible for notifying the Research Ethics Committee (REC) that issued a favourable opinion within 90 days of the end of study using the appropriate End of Study (EOS) Declaration Form ([Ending your project - Health Research Authority](#)).

The SRA will use the appropriate email template in Form 51.019A to advise the CI of this process. A copy of the correspondence will be filed within the study e-folder, and SReDA will be updated in accordance with SOP 51.022.

Where the EOS Declaration is not received, the SRA will follow the escalation process described in Section 3.1.

3.2.2. End of Study Declaration – Studies Submitted to HRA and HCRW Only

For studies that have received both a favourable REC opinion and HRA and HCRW Approval, the end of study only needs to be declared to the REC, as described in section 3.2.1.

For studies that have received a HRA and HCRW Approval, but did not require REC review, the Sponsor Research Facilitator (SRF) will issue the relevant email template in Form 51.019A to advise the CI of the end-of-study notification requirements. The CI must notify HRA directly by email at approvals@hra.nhs.uk and include their Integrated Research Application System (IRAS) ID and contact information.

3.2.3. End of Study Acknowledgement – Studies Submitted to a REC

Following the submission of the EOS Declaration Form, the SRA will request the acknowledgment correspondence from the REC. Where necessary, the SRA may need to follow up with the study team or the REC to obtain this acknowledgment. The SRA will ensure this acknowledgment is appropriately stored in the ethics section of the e-folder in the common drive, along with the EOS Declaration Form.

3.2.4. End of Study Acknowledgement – Studies Submitted to HRA and HCRW Only

Following the EOS notification by email to the HRA and HCRW, the SRF will request the acknowledgment correspondence from the HRA and HCRW. Where necessary, the SRF may need to follow up with the study team or the HRA to obtain this acknowledgment. The SRF will ensure this acknowledgment is appropriately stored in the e-folder in the common drive.

3.2.5. Trial Close out and Archiving

When the EOS Acknowledgement has been received, the SRA will notify the relevant SRC and Information Officer (IO). The IO will update CPMS portfolio database and the IO/SRC will proceed with archiving arrangements as detailed in SOP 51.025.

3.2.6. Final Report – Studies submitted to a REC

A final report is required for all project-based research that has received a favourable opinion from a REC, with the exception of research tissue banks and research databases.

Following receipt of the EOS Declaration Form, the SRA will issue the relevant email template in Form 51.019A to the CI to acknowledge receipt and remind the CI of the requirement to submit the final report.

The CI is responsible for submitting the final report to the REC within 12 months of the end of study using the Final Report Form: [Submit your Final Report - Health Research Authority](#).

Research tissue banks and research databases are not required to submit a final report using the standard REC Final Report Form, as there is no standard reporting format for these study types. However, any reporting requirements specified by the approving bodies must still be met.

3.3. CTIMPs/CIMDs

3.3.1. CTIMPs/CIMDs submitted not through the Combined Review

The CI/PM is responsible for declaring the end of a study to the Research Ethics Committee (REC) that gave a favourable opinion within 90 days of the study ending following the process in 3.2.1.

3.3.1.1. End of Study Declaration – Notifying MHRA

For CTIMPs/CIMDs, the declaration of end of trial must be sent to MHRA within 90 days of the global end of trial date and within 15 days of the global premature end of trial.

For CTIMPs/CIMDs that were not submitted through the Combined Review process, the MHRA End of Trial Form and MHRA cover letter (Form 51.019B) is completed by the SRC (or PMs if the study is run through GOCTU), for CTIMPs, using MHRA Submissions ([MHRA Portal](#)) by selecting *Medicines & E-cigarettes*. Select 'Clinical Trial' as the Regulatory Activity and 'CT – EOT' from the Regulatory Sub Activity dropdown list. More information can be found on the MHRA website: [Clinical trials for medicines: manage your authorisation, report safety issues - GOV.UK](#).

For CIMDs, manufacturers are required to email the MHRA when a clinical investigation of a medical device comes to an end.

3.3.1.2. Early Termination – Notifying MHRA

For early termination of a CTIMP/CIMD that was not submitted through the Combined Review process, that has been terminated prematurely, , or it has been decided that the study will not start (following MHRA CTA approval - the MHRA End of Trial Form and MHRA cover letter (Form 51.019B) is completed by the SRC (PM's if the study is part of GOCTU) and submitted in IRAS within 90 days.

For all CTIMPs/CIMDs, this must also be stored in the TMF as it is an essential document. The SRA/IPM will also cross-check the form against SReDA to ensure study information is correctly recorded (See SOP 51.022).

3.3.2. CTIMPs submitted through Combined Review

The CI/PM is responsible for declaring the end of a study to the Research Ethics Committee (REC) that gave a favourable opinion within 90 days of the study ending and 15 days for those terminated early, following the process in 3.2.1.

3.3.2.1. End of Study Declaration – Notifying MHRA

For CTIMPs submitted through combined review, the end of trial form will be completed by the PMs in the new part of IRAS. The SRC will then approve end of study submission, this automatically submits the notification to the REC and MHRA.

3.3.3. End of Study Acknowledgement

When the EOS Declaration Form from REC is sent by the research team to R&I, the SRA/IPM will follow the process detailed in 3.2.3.

For all CTIMPs/CIMDs, MHRA acknowledgement of the EOS Declaration form is also required. The SRA/IPM will ensure this acknowledgement is filed in the TMF and appropriately stored in the regulatory MHRA section of the e-folder in the common drive. Sponsor Oversight Checklist (Form 51.018A) will be completed by Research Coordinator SRC with the end of trial information for CTIMPs. The MHRA acknowledgment will be shared by the RC to the CI, Project Manager and all relevant R&I stakeholders so the archiving process can begin as detailed in SOP 51.024. The date MHRA acknowledgement is received will be recorded on SReDA by the SRA/IPM as this is when the retention period of the TMF begins.

3.3.4. Trial Close-out

When the EOS Declaration form has been received by R&I, the SRC and IO will follow the steps in 3.2.4 and arrange archiving with the study team as detailed in SOP 51.024.

If the trial is a CTIMP or involves dispensing medicines, R&I Pharmacy must also be notified to close the study as per SOP 22.026. The monitoring team will also be notified where a close-out visit or monitoring close-out activity is required, in accordance with SOP 53.012

3.3.5. Final Report

For CTIMPs/CIMDs, this must be submitted through IRAS and all other research will be submitted on the HRA website using the following link: <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/final-report-form/>.

Please note for research tissue banks and research databases, there is no standard format for final reports. For CIMDs, a copy of the final report will be sent to the MHRA when it is available.

3.3.6. Summary of Results to MHRA

For CTIMPs/CIMDs, projects registered on public databases (for example UKCRN, Clinicaltrials.gov and the European Union Drug Regulating Authorities Clinical Trials (EudraCT) website (<https://eudract.ema.europa.eu/>)) must have their entries updated to add the summary of results within 12 months from the end of trial.

Once the public database has been updated, a confirmation email that the summary of results has been added is sent to CT.Submission@mhra.gov.uk by the CI/PM.

Where this is a multi-national study, this is the end of the study in all participating countries and not just in the UK.

3.4. Analysis and Publications

Final analysis of the data (following 'lock' of the study database) and report writing is normally considered to occur after formal declaration of the end of the research. Findings to be submitted for publication in a journal will be done within 12 months of the end of study. . Please note for studies involving human tissue, the analysis of the samples will be undertaken as part of the data collection before the end of study is declared.

3.5 Public Databases

Projects registered on public databases (e.g. ISRCTN, Clinicaltrials.gov) will also have their entries updated to reflect that the project has ended as necessary. The Chief Investigator (CI) must ensure that, within 12 months of the end of the clinical trial, a summary of the results is:

- Published in the same public registry (or registries) in which the trial was originally registered; and
- Prepared in a format that is understandable to laypersons.

The CI is also responsible for ensuring that this lay summary is made available to all relevant persons. Relevant persons include trial participants, or where applicable, individuals who provided consent on their behalf (e.g. parents/guardians of minors), and, where a participant is unable to receive the information (e.g. due to incapacity or death), a person engaged in their care or interested in their welfare (such as a legal representative or next of kin).

For CTIMPs, the CI/PM must ensure that summary results are published within 12 months of the end of trial in the same public registry or registries in which the trial is registered, unless a deferral or waiver applies. Where a study was previously registered only in EudraCT, the CI/PM will confirm whether registration in a public registry is required in accordance with current HRA/MHRA transparency guidance.

The CI/PM will provide evidence to the SRC that the summary of results has been published in the required registry/registries and that arrangements have been made to offer the lay summary to participants and/or other relevant persons, where applicable. This evidence will be filed in the TMF or Sponsor e-file, as applicable.

4. Referenced documents

- Form 51.019A - Project Status E-Mail Template
- Form 51.019B - MHRA Cover Letter
- SOP 22.026 - Closure of a clinical trial – pharmacy process
- SOP 51.008 - Handling non-compliance with Good Clinical Practice (GCP) and/or the trial protocol in clinical research sponsored, co-sponsored or hosted by NHS Greater Glasgow and Clyde
- SOP 51.021 - Review and Approval of Modifications for Research Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow
- SOP 51.022 - Research & Innovation Data & Administration tasks
- SOP 51.024 - Archiving Essential Documents from Clinical Research – Process for a GGC Sponsored/Co –Sponsored CTIMP and/or CIMD
- SOP 51.025 - Archiving Essential Documents from Clinical Research – Process for a Sponsored Non CTIMP
- Form 51.018A - Sponsor oversight checklist
- HRA Website, Final Report - <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/final-report-form/>
- SOP 53.012 - Monitoring Clinical Research - Site Close Out Monitoring Visit

5. Related documents

- N/A

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	07/04/2017	Release of first version	No
2.0	17/12/2018	Responsibility for compliance has moved from the coordinator, to the CI.	No
3.0	11/02/2022	Change of author, addition of University Research Governance in staff category, addition of section 5.7 – study report, comment in section 5.2.1 about storage end of study reports and version updated. Inclusion of information about the new Final Report Form.	No
4.0	22/04/2025	Change of author. Addition of combined review process. 2 new forms added.	No
5.0	01/10/2026	Addition of updated ICH GCP regulations to include the results at the end of a study are shared with participants. Addition of Innovation sponsor co-ordinator.	No

This SOP is a controlled document. The current version can be viewed on the R&I website, GCTU website and R&I's Q-Pulse account.

Any copy reproduced from the website may not, at time of reading, be the current version.