SOP number	**51.019**	Version	**4.0**
Title	**Sponsor – End of study procedures**		

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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			
Sponsor Research Co-Ordinator	X			
Chief Investigators			X	
Principal Investigators			X	
Research Governance Manager			X	
Commercial Research Co-Ordinator				X
Sponsor Pharmacy				X
Clinical Trial Monitors				X
Project Managers				X

1. Scope

This procedure applies to NHS Greater Glasgow and Clyde (NHSGGC) R&I Department.

2. Purpose

The purpose of this SOP is to define the process for notification of end of research projects Sponsored or Co-Sponsored by NHSGGC.

This SOP will be followed when the Sponsor representative becomes aware of the study end from research team or other R&I staff.

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 the study end within 3 months or have past their study end date to ensure R&I have visibility of all project statuses. An email is sent to the PI/CI (Principle Investigator/ Chief Investigator) using Form 51.019A (Project Status Email Template) by the SRA (Senior Research Administrator). The SRA will also update SReDA (Scottish Research Database Application) when the PI/CI has confirmed the project status. If no response is received from the PI/CI then two further emails will be sent including the wider research team (Including the CI's line managers) to ascertain

if the study has ended. If there is no response after all 3 emails over 3 months then this will be escalated to the Research Governance Manager (RGM) and reported as a Non-Compliance. The RGM will then try to contact the Investigator to inform them the trial will close if an amendment is not submitted to extend. Following this the RGM will confirm back to the SRC if the trial is to close.

If the PI/CI wants to extend the study end date, an amendment needs to be submitted to the SRC.

3.2. Non-CTIMPs

3.2.1. End of Study Declaration – Studies submitted to REC

The end of study will be defined in the study protocol and the reviewing bodies need to be notified of the end of study.

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 using the appropriate form. There are two separate forms depending on the study type found on HRA's website (Ending your project - Health Research Authority).

The SRA/Innovation Project Manager (IPM) will use the appropriate email template in Form 51.019A to advise the CI of this process. The SRA/IPM will then file this form in the e-folder in the common drive and update SReDA as per SOP 51.022. If no response is received from the PI/CI then two further emails will be sent, including the wider study team, to obtain the EOS Declaration. If there is no response after all 3 emails over 3 months then this will be escalated to Research Governance Manager and reported as a Non-Compliance The RGM will then try to contact the Investigator to inform them the trial will close if an amendment is not submitted to extend. Following this the RGM will confirm back to the SRC if the trial is to close.

3.2.2. HRA and HRCW studies

Studies with both a REC favourable opinion and HRA and HCRW approval only need to declare the end of study to the REC, as described in section 3.2.1.

For studies that have HRA and HCRW approval, but did not require REC review, the Sponsor Research Facilitator (SRF) will issue an email based on the template in Form 51.019A to the PI/CI the CI will need to notify HRA directly 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 REC

When the EOS Declaration Form is sent by the research team to R&I, the SRA/IPM will request the acknowledgment correspondence from the REC. The SRA/IPM may need to chase the study team or REC for this acknowledgement. The SRA/IPM will make sure 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. Trial Close out

When the EOS Declaration form has been received by R&I, the SRA/IPM notifies the relevant SRC, and Information Officer (IO). The IO will update CPMS portfolio database and makes archiving arrangements with the study team as detailed in SOP 51.025.

3.2.5. Final Report – Studies submitted to REC

The final report is for all project-based research (except for research tissue banks and research databases) that has been reviewed by a REC.

The SRA/IPM will issue an email based on the template in Form 51.019A to the PI/CI to acknowledge receipt of the EOS Declaration form and inform the CI to submit the final report. This report must be submitted within 12 months of the EOS Declaration form using the Final Report Form.

Please note for research tissue banks and research databases, there is no standard format for final reports.

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), using MHRA Submissions via the Human Medicines Tile. 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.

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

Early termination of a CTIMP/CIMD that was not submitted through the Combined Review process, has been terminated prematurely after MHRA issued CTA, and it has been decided that the study will not start. 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 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 can 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 make sure 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) should be completed by Research Coordinator SRC with the end of trial information for CTIMPs as necessary. 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 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 makes archiving arrangements 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).

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 should 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 data base) 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 should be done within 12 months of the end of study. Please note for studies involving human tissue, the analysis of the samples should be undertaken as part of the data collection before the end of study is declared.

3.5 Public Databases

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/)) should also have their entries updated to reflect that the project has ended as necessary.

4. Referenced documents

- Form 51.019A - Project Status E-Mail Template
- Form 51.019B - MHRA Cover Letter
- 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/

5. Related documents

- None

6. Document history

Version	Date	Description
1.0	07/04/2017	Release of first version
2.0	17/12/2018	Responsibility for compliance has moved from the coordinator, to the CI.
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.
4.0	22/04/2025	Change of author. Addition of combined review process. 2 new forms added.