Standard Operating Procedure			**51.019**
Sponsor – End of study procedures			
Version	**3.0**		
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Approved by	Melissa Robert	Signature	Date
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1. SOP Category
Trial Management

2. Staff Category
Research and Innovation (R&I)
- Sponsor representative (Research Coordinator)
- Project Manager if delegated responsibilities from a Research Coordinator
- Chief Investigator and relevant designee(s)
- University Research Governance

3. Scope
This procedure applies to NHS Greater Glasgow and Clyde (NHS GG&C) R&I Department.

4. Purpose
The purpose of this SOP is to define the process for notification of end of research projects sponsored or co-sponsored by NHS GG&C.

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

5. Procedures
5.1. Background
The definition of the end of the study (not necessarily the end of the recruitment period) should be in the research protocol. If the definition is not provided in the research protocol or REC/MHRA/R&I submission forms, it should be considered to be the date of last participant last visit.

Where the definition differs for MHRA and REC then the end of trial will be considered separately for the 2 review bodies.

It is a condition of the Research Ethics Committee (REC) favourable opinion and MHRA approval that both are notified of the end of a study and this includes premature termination. The CI, or designee, will ensure that the appropriate form is completed and submitted to REC/MHRA within the required timeframe.

5.2. End of Study Declaration

5.2.1. Submission of declaration to REC

The CI, or designee, will notify the REC, which gave the original favourable opinion, of the end of a study within 90 days of the end of the study or within 15 days if the study is terminated prematurely. This notification should be given using the National Research Ethics Service (NRES) End of Study Declaration Forms. There are two separate forms:

- Clinical Trials of Investigational Medicinal Products (CTIMPs) - Declaration of the end of a Clinical Trial form
- All other research - Declaration of the end of a study

Current versions of both forms, as well as further guidance specifically from the REC can be found via NRES web page. The REC will acknowledge receipt of submitted forms.

Where a project has Health Research Authority (HRA) Approval and was not reviewed by an NHS REC, the HRA should be informed that the project has ended. Notification should be sent by email to approvals@hra.nhs.uk including the Integrated Research Application System (IRAS) ID and your contact information.

In addition to the End of Study Declaration, the REC will also require a final study report, known as the Final Report Form (from the CI or designee).This must be submitted within 12 months of submission of the End of Study Declaration. The Final Report Form can be accessed, completed and submitted online via the HRA website at the following address: https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/final-report-form/. Submission via this webform will share this report with the HRA and REC. A copy of the report should also be submitted to Sponsor and this will be saved in the appropriate common drive folder.

If the study never started and it has been decided that it will not start, the REC should be informed in writing.

For clinical trials of investigational medicinal products (CTIMPs) submitted via the Combined Review Service, the Final Report Form can be completed and submitted in the new part of IRAS, and guidance for this process can be found here: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/combined-ways-working-pilot/

5.2.2. Submission to EudraCT and MHRA

A Declaration of the end of a Clinical Trial form should be completed and sent to the MHRA and the regulatory authority in other Member States where applicable, by the CI or designee, within 90 days of the end of the trial. The Declaration of the end of a Clinical Trial form is available from the EudraCT: European Clinical Trials website.

If the study has been terminated prematurely, the form should be submitted to the MHRA within 15 days of date of termination.

If the study never started and it has been decided that it will not start, the MHRA should be informed in writing, by the CI or designee, and the premature termination form can be used.

Once the Declaration of the end of a Clinical Trial form has been received by the MHRA it is not possible to submit any further amendments to the trial and only the end of trial study report will be accepted. The CI, or designee, must submit the end of trial summary results to EudraCT within 12 months of the end of the trial (6 months for pediatric trials), in accordance with current EU Commission guidelines. Subsequently, an email confirming that the summary report has been uploaded, will be submitted to the MHRA at: ct.submission@mhra.gsi.gov.ukIf reporting results within 12(6) months is not possible, an email

should be sent to the MHRA, at this address: clintrialhelpline@mhra.gsi.gov.uk, explaining why the results are not available and estimating when they will become available. Once the report can be submitted, the confirmatory email should be sent to this address: ct.submission@mhra.gsi.gov.uk.

The MHRA may request a copy of the final report of a Clinical Investigation of a Medical Device (CIMD).

Where this is a multi-national trial this is when the study has ended in all participating countries and not just in the UK. If the trial is no longer active in the UK, but is ongoing at other European or Global sites, the MHRA may be notified of this fact.

Sponsor Oversight Checklist (Form 51.018A) should be completed by Research Coordinator with the end of trial information for CTIMPs as necessary.

5.3. Notification to sites and R&I offices

The following documents will be submitted to coordinating centres and sites:

Documents	Sites	Coordinating Centres
End of Trial Declaration Form	✓	✓
REC acknowledgement (if applicable)	✓	✓
MHRA acknowledgement (if applicable)	✓	✓
Letter to PI and site staff	✓	

5.4. 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.

5.5. Study Report

The Sponsor and the CI will review and approve all study reports supplied by the data management center.

5.6. Site close-down

The CI and Research Coordinator should receive confirmation that sites have completed actions from monitoring close-out visit (SOP 53.004) and site file(s) have been archived as necessary.

6. Referenced documents

Form 51.01851.018A – Sponsor oversight checklist
SOP 53.00453.004 – Monitoring Clinical Trials
EUDRACT Website - https://eudract.ema.europa.eu/
HRA Website, Final Report - https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/final-report-form/

7. Related documents

None

8. 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.