SOP number	**53.003**	Version	**4.0**
Title	**Temporary halt or early termination of clinical trials of investigational medicinal products**		

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Approved by Signature	Chloe Cowan Date
Released by Signature	Julie Brittenden Date

SOP category	NHS GG&C Sponsor Governance

Staff category

Staff Category	**R**	**A**	**C**	**I**
Research Governance Manager		X		
Lead Pharmacist Clinical Trials R&I	X			
All R&I Staff	X			
Chief Investigators (NHSGGC Sponsored and Co-Sponsored trials)	X			
Glasgow University Research Governance Team	X			

1. Scope

This procedure applies to all trials Sponsored/Co-Sponsored and hosted by NHS Greater Glasgow and Clyde Board (NHSGGC) and staff involved in this activity.

2. Purpose

The purpose of this SOP is to describe how NHS Greater Glasgow & Clyde (NHSGGC) halts or terminates early non commercial (academic) clinical trials Sponsored or Co-Sponsored by NHSGGC in compliance with Regulation 27 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument 2004/1031) as amended.

3. Procedures

3.1. Temporary halt of a trial or a site involved in a trial

3.1.1. The R&I Director, a Sponsor's representative and/or the Investigator is responsible for the decision to temporarily halt or terminate early a clinical trial, e.g. following a recommendation from an independent data monitoring committee, a series of non-compliance or safety issue. If a trial is temporarily halted or terminated early the Glasgow Health Science Partnership Regulatory Affairs Group, (GHSP RAG) will be informed and may make recommendations on the future management of the trial.

3.1.2. An appropriate representative of the Sponsor, in conjunction with the Chief Investigator, must notify the Medicines and Healthcare products Regulatory Agency (MHRA) and relevant ethics committee within 15 calendar days of the decision to halt the trial or halt a trial site.

3.1.3. The notification must be made as a substantial amendment to the MHRA using the Notification of Amendment form, clearly explaining what has been halted (i.e. stopping recruitment and/or interrupting treatment of subjects already included) and the reason(s) for the halt.

3.1.4. NHSGGC and the Investigator may halt a trial as an urgent safety measure in order to protect the subjects of a clinical trial against any immediate hazard to their health and safety. Urgent safety measures can be implemented immediately and prior to authorisation from the MHRA and relevant ethics committee. In that case, SOP 53.001 handling urgent safety measures for clinical trials of investigational medicinal products must be followed. The MHRA must be notified immediately, (or no later than 3 calendar days from the date the measures were taken) the MHRA and relevant ethics committee of the measures taken and the circumstances.

3.2. To restart a trial or a trial site

3.2.1. To restart a trial or a trial site that has been temporarily halted, an appropriate representative of the Sponsor, in conjunction with the Chief Investigator, shall make the request as a substantial amendment to the MHRA and relevant Ethics Committee using the Notification of Amendment form.

3.2.2. The substantial amendment notification must include evidence that it is safe to restart the trial.

3.2.3. The R&I Director or a Sponsors' representative is responsible for the decision to restart a trial or a trial site. The decision to restart a trial may only be taken following approval of the substantial amendment by the MHRA and relevant Ethics Committee. The Chief Investigator will be notified of the restart date and any relevant conditions.

3.2.4. GHSP RAG will be informed when the trial is re-started and may make recommendations.

3.3. Trial does not recommence

3.3.1. This following procedure is only relevant when a trial and not individual trial sites does not recommence.

3.3.2. If the trial does not recommence following a temporary halt, an appropriate representative of the Sponsor must submit an End of Trial Declaration form to the MHRA and relevant Ethics Committee within 15 calendar days of the decision. This should be done in conjunction with the Chief Investigator. This form can be accessed at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1022119/declaration_end_trial_form_final_29.09.21.doc

3.3.3. A cover letter should also be submitted which includes:

- Name and address of Sponsor's legal representative
- Title of trial
- EudraCT number
- Trial protocol code number
- Date of end of trial in member state concerned
- Date of end of complete trial in all participating centres

3.3.4. When the trial is terminated early, the end of clinical trial report should also provide the following information:

- Justification of the premature ending of the trial
- Number of patients still receiving treatment at the time of study termination
- Proposed management of patients receiving treatment at time of study termination
- Consequences for the evaluation of results

4. Referenced documents

- SOP 53.001 - Handling urgent safety measures for clinical trials of investigational medicinal products
- End of Trial Decleration Form - https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1022119/declaration_end_trial_form_final_29.09.21.doc

5. Related documents

- Glasgow Health Science Partnership Regulatory Affairs Group Terms of Reference
- SOP 51.008 Handling non compliance with Good Clinical Practice (GCP) and/or the trial protocol in clinical research
- SOP 53.002 The Handling of Poor Quality and Fraud in Clinical Research

6. Document history

Version	Date	Description
1.0	18/06/09	Release of Version 1.0
1.1	04/11/13	Change to staff category, sponsor representatives or NHS staff who can stop and start trials. Inclusion of procedures when a trial site is temporarily halted.
2.0	15/07/2016	Updated to template v1.4.
3.0	04/01/2019	Temporary change to Author. Revised Governance structures (RAGs) updated. GU Governance staff added in staff category. "Approved" & "Released by" updated. No changes made to process.
4.0	25/01/2024	Change back to original author, RACI matrix added, clarification on halt due to urgent safety measure. Update link to end of trial declaration form link.