SOP number	**53.001**	Version	**4.0**
Title	**Handling Urgent Safety Measures for Clinical Trials for Investigational Medicinal Products**		

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Approved by Signature	Chloë Cowan	Date
Released by Signature	Chloë Cowan	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			
R&I Sponsor Co-Ordinators	X			
R&I Commercial Co-Ordinators	X			
R&I Senior Managers				X
R&I Sponsor Pharmacy				X
R&I Monitors				X
Chief Investigators (Sponsored/Co-Sponsored Trials)			X	
Principal Investigators			X	
QA lead Beatson CRF				X
Glasgow University Research Governance Team				X
All R&I Staff				X

1. Scope

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

2. Purpose

The purpose of this SOP is to describe the process for handling Urgent Safety Measures in compliance with Regulation 30 of the Medicines for Human Use (Clinical Trials) Regulations 2004 (Statutory Instrument 2004/1031) for clinical trials Sponsored, Co-Sponsored or Hosted by NHS Greater Glasgow and Clyde (NHSGGC).

3. Procedures

3.1. General

The Clinical Trials Regulations make provision for the Sponsor and Investigator to take appropriate Urgent Safety Measures (USMs) to protect a research participant from an immediate hazard to their health and safety.

NHSGGC staff and Chief and/or Principal Investigators may take appropriate Urgent Safety Measures in order to protect the participants of a clinical trial against any immediate hazard to their health and safety. Those measures can be implemented immediately and prior to authorisation from the Sponsor, MHRA and relevant ethics committee. Examples of possible measures include deviations from the protocol or a temporary halt to the study.

Any urgent safety measure relating to a CTIMP should be communicated to the MHRA immediately.

If the Urgent Safety Measures are taken in a period during which a disease: a) is pandemic; and b) is a serious risk to human health or potentially a serious risk to human health, the MHRA and relevant ethics committee must be notified of the measures taken and the circumstances.

The Pharmacovigilance Office of the appropriate Sponsor must be notified immediately of any Suspected Unexpected Serious Adverse Reactions (SUSARS) relating to the USM

3.2. Responsibilities of NHSGGC for Hosted Research

If urgent safety measures are taken for a trial Hosted by NHSGGC, the external Sponsor must be notified immediately of the measures taken. The external Sponsor is responsible for notifying the MHRA and relevant ethics committee of the measures taken and the circumstances.

3.3. Responsibilities of NHSGGC for NHSGGC Sponsored or Co-Sponsored Research

The Chief and/or Principal Investigator, Pharmacovigilance Manager, the Lead Clinical Trials Pharmacist or the Research Governance Manager is responsible for the decision to take appropriate Urgent Safety Measures in order to protect the participants of a clinical trial against any immediate hazard to their health or safety. The chair of the Glasgow Health Science Partnership Regulatory Affairs Group (or representative) may also make recommendations to implement Urgent Safety Measures.

NHSGGC staff or Investigators will phone the MHRA Clinical Trial Unit within 24 hours to discuss the event with a medical assessor. The Sponsor must then follow-up with notification in writing within three calendar days of the action being taken. The notification will be in the form of a Substantial Amendment and will describe the event, the measures taken and justification for the measures taken.

The main research ethics committee must be notified immediately and in any event within three calendar days, that such measures have been taken and the reasons. NHS R&D offices and/or trial sites for those involved with the trial will require notification.

The substantial amendment will include a covering letter detailing the measures taken, reason for the measures taken, name of MHRA contact, notification of amendment form, action plan and any supporting documentation.

If a Serious Breach has occurred SOP 51.009 - Notification of serious breaches of Good Clinical Practice must be followed.

4. Referenced documents

- SOP 51.009 - on notification of serious breaches of Good Clinical Practice and/or the trial protocol for clinical trials of investigational medicinal products.
- SOP 51.021 – Sponsor Review and Approval of Amendments

5. Related documents

- Statutory Instrument 2004/1031: The Medicines for Human Use (Clinical Trials) Regulations 2004
- 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
- SOP 55.001 - Pharmacovigilance in Clinical Trials of Investigational Medicinal Products (Glasgow Clinical Trials Unit)

6. Document history

Version	Date	Description
1.0	07/07/09	Release of Version 1.0
1.1	30/09/09	Inclusion of new paragraph (4.1.3) – measures taken during a pandemic.
1.2	04/11/13	Change of staff category to highlight sponsor responsibilities, decision making changes from director to lead clinical trials pharmacist and research governance manager
2.0	15/07/2016	Updated to template v1.4.
3.0	04/01/2019	Temporary change to Author, GU Governance staff added under staff category. “Approved & “Released by” updated. Revised governance reporting groups (RAGs) updated. No changes made to process.
4.0	04/10/2024	Update to new format, minor changes and clarifications.

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