STANDARD OPERATING PROCEDURE FOR REPORTING URGENT SAFETY MEASURES FOR CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS (CTIMPs)

SOP NUMBER:	TASC SOP68 v2
AUTHOR:	Joana Rocha
EFFECTIVE DATE:	28 Apr 2026
REVIEW DATE:	05 Mar 2028

1. PURPOSE

This Standard Operating Procedure (SOP) describes the process to be followed when Urgent Safety Measures (USMs) need to be put in place in relation to Clinical Trials of Investigational Medicinal Products (CTIMPs) which are sponsored or co-sponsored by the University of Dundee (UoD) and/or NHS Tayside (NHST).

2. SCOPE

This SOP should be used in situations where the Sponsor, Chief Investigator (CI) or Principal Investigator (PI) or delegate must ensure urgent action is taken to protect the participants of a CTIMP against any immediate hazard to their health or safety.
The Sponsor procedure complies with the requirements of the Medicines for Human Use (Clinical Trial) Regulations 2004 and the European Pharmacovigilance Regulations (effective 2012) and subsequent amendments.

This SOP applies to members of staff associated with and managing CTIMPs that are sponsored or co-sponsored by the UoD and/or NHST.

3. RESPONSIBILITIES

Investigator (CI, PI) or delegate:

- must notify the CI/PI immediately once aware of issues that may put the health or safety of participants at risk.
- must take appropriate action to protect participants from any immediate hazard to their health or safety.
- must notify the Sponsor of any safety concerns as well as any USMs implemented.
- for multi-location trials, the CI or delegate must notify host locations of the need to implement USMs.

Sponsor (Research Governance or TASC Pharmacovigilance):

- must notify the CI immediately if aware of issues that may put the health or safety of participants at risk.

- must ensure that any necessary USM's are implemented, and that the licensing authorities (Medicines and Healthcare products Regulatory Agency (MHRA) or others) which approved the trial have been notified within the specified timelines.

4. PROCEDURE

4.1 What is an urgent safety measure

During the course of a trial, new safety information may necessitate an immediate change in trial procedures or a temporary halt to the trial to protect participants from any immediate hazard to their health or safety. These modifications may be implemented without first notifying the licencing authority and ethics committee.

Where urgent action is required as a result of a Suspected Unexpected Serious Adverse Rection (SUSAR), the Sponsor should also consider whether an USM is required.

A temporary halt can also be part of an USM; refer to TASC SOP on Modifications.

If the USM includes unblinding a participant's allocation to treatment, please refer to TASC SOP on Randomisation, Blinding and Code-Breaking.

4.2 Reporting USM to Sponsor

4.2.1 Trial Teams

a) On discovering a safety issue, the Investigator or delegate must contact the Sponsor immediately to discuss further action by emailing tay.pharmacovigilange@nhs.scot marking it "Urgent safety measure". The Sponsor (TASCgovernance@dundee.ac.uk or 01382 383297) and CI should be included in these communications.

4.2.2 TASC Pharmacovigilance (PV) Committee

a) On discovering the safety issue, the PV Committee Chair or delegate must contact the Sponsor (TASCgovernance@dundee.ac.uk or 01382 383297) and trial CI immediately to discuss further action.

4.3 Reporting the USM to the licensing authority: (see appendix 1)

a) The Sponsor and the CI will liaise and contact the MHRA Clinical Trials Helpline (020 3080 6456) within 24 hours of any measures being taken, and no later than 3 days from the date the measures are taken.

b) The Investigator/delegate or Sponsor will provide the licensing authority with a written notification of the measures taken within 7 days from the date the measures were taken, or as soon as possible during any period where a disease is pandemic and is a serious or potentially serious risk to human health.
The USM written notification will be submitted via ***Integrated Research Application System*** (IRAS). No additional notification is required to the Research Ethics Committee (REC).

The licensing authority will decide whether the measure taken is a USM and communicate the outcome to the Sponsor.

c) If the licensing authority agrees the measure is a USM, a substantial modification will be submitted through **IRAS** by the Investigator or delegate. This must be submitted within 2 weeks of notification.

Any potential delays in submission should be discussed with the licensing authority at the initial or follow-up telephone call.

Note: The USM-related modification must not include any changes different to those required as a USM.

4.4 Reporting the USM to European Member States

If applicable, the Investigator/delegate or Sponsor are required to notify all European Member States concerned through the European Medicines Agency's ***Clinical Trial Information System*** (CTIS) of such events without delay, but no later than 7 days from the date the measures were taken.

4.5 Notification of USM to Host Institutions

For multi-location trials, the Investigator or delegate will be responsible for notifying host locations of the need to implement a USM. This should be done by contacting the local R&D department and PI directly.

4.6 Notification of a USM to TASC PV Committee

For trials sponsored or co-sponsored by the UoD and/or NHST the TASC PV Committee will be notified by the Sponsor of any USMs, halt of the trial or premature trial closure because of the implementation of the USMs.

5. ABBREVIATIONS & DEFINITIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CTIS	Clinical Trial Information System
IRAS	Integrated Research Application System
NHST	NHS Tayside
PI	Principal Investigator
PV	Pharmacovigilance
REC	Research Ethics Committee
SUSAR	Suspected Unexpected Serious Adverse Reaction
SOP	Standard Operating Procedure
UoD	University of Dundee
USM	Urgent Safety Measure

6. ASSOCIATED DOCUMENTS & REFERENCES

None.

7. DOCUMENT HISTORY

History prior to 2021 is in the archived SOPs available from TASC Quality Assurance Dept.

Version Number:	Reviewed By (Job Title):	Effective Date:	Details of editions made:
1	Joana Rocha (TASC PV Monitor)	05/03/2026	New
2	Joana Rocha (TASC PV Monitor)	28/04/2026	Updated in accordance with the new Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

8. APPROVALS

Approved by:	Date:
Dr Steve McSwiggan, Senior R&D Manager NHS Tayside	30 Mar 2026
Dr Valerie Godfrey, TASC Quality Assurance Manager, on behalf of TASC Clinical Research Guidelines Committee	27 Mar 2026

Appendix 1

Table 1: MHRA Flowchart summarising the process of notifying the licensing authority of a potential USM.