SOP-QA-42 V2

Title: Urgent Safety Measures

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Author: Louise King, Research Governance Manager	
QA Approval: Richard Cowie, QA Manager	
Approver: Prof Seshardi Vasan, R&D Director	
Approver: Prof David Blackbourn, Head of School	

GRAMPIAN CLINICAL RESEARCH OFFICE

NHS Grampian

1495 UNIVERSITY OF ABERDEEN

Document History

Version	Description of update	Date Effective
1	New SOP	30-11-21
2	Removal of reference to MDCIs as not relevant Addition of IRAS number and email address for MHRA, removal of reference to EudraCT number at 3.3 Clarification on information required for notification and addition of process for combined review studies at 3.5	19-12-24

1. Scope

1.1 This SOP applies to any individual delegated the task of identifying, recording, reporting, and implementing an Urgent Safety Measure (USM) for research projects sponsored or co-sponsored by University of Aberdeen (UoA) and/or NHS Grampian (NHSG).

1.2 For research projects which are sponsored externally to the UoA or NHSG, local researchers and support staff should refer to the respective Sponsor's procedure and any timelines for handling Urgent Safety Measures.

2. Responsibilities

Chief Investigator (CI)	Reporting and Implementation of Urgent Safety Measures.
Principle Investigator (PI)	Reporting and Implementation of Urgent Safety Measures.
Sponsor	Reviewing USMs and ensuring they are reported to the REC and MHRA and substantial amendment submitted.

3. Procedure

Reporting of Urgent Safety Measures to Sponsor, REC and MHRA (CTIMPs)

3.1 The Sponsor, CI or PI may implement USM to protect trial participants from immediate harm. The CI can deviate from the trial protocol or implement a change to the trial protocol to eliminate an immediate hazard to trial participants; without prior approval from the REC or MHRA. This shall be reported to the Sponsor immediately by email to pharmaco@abdn.ac.uk.

3.2 Non-CTIMPs: the CI shall also contact and discuss the issue with the REC, ideally **within 24 hours** of measures being taken, and no later than 3 days from the date the measures being taken.

3.3 CTIMPs: the CI shall also contact and discuss the issue with a medical advisor at the MHRA Clinical Trials Unit, by calling (+44) 020 3080 6456, ideally **within 24 hours** of measures being taken, and no later than 3 days from the date the measures being taken.

Below is the information the MHRA will require for the call:

- IRAS ID and/or the EudraCT number of the trials for which the USM action has been taken
- Other ongoing trials (UoA/NHSG sponsored) with the same Investigational Medicinal Product (IMP)
- Whether any other trials with a different sponsor may be impacted
- The affected IMPs (including developmental/Commercial names)
- Nature of the safety concern and whether it has been reported as a SUSAR
- What USM actions have been taken and when
- The number of UK subjects who are currently receiving the IMP, the number of subjects who received it and the number affected by the USM
- Contact details in case of further questions.

Where this information is not available during the initial call it should be provided as soon as possible.

If you are not able to report a USM to the MHRA by telephone please send an email to clintrialhelpline@mhra.gov.uk within 3 days of taking urgent measures. The subject of the email shall be 'USM for trial IRAS ID/EudraCT number'. You need to explain in the email the USM implemented, the reason and why you did not report it via telephone. An MHRA assessor will contact you and provide advice regarding further actions

3.4 The CI must discuss the implications of the urgent safety measure on the conduct of the trial with the Sponsor as a matter of urgency. The Sponsor will complete a risk assessment to determine if the study should continue.

3.5 The CI must then provide written notification to the MHRA (CTIMPs), REC, Sponsor, PIs of additional sites (if a multi-centre study) and relevant NHS Research and Development (R&D) offices within **3 days** of the measures being taken. The notification should describe the event, the measures taken and the justification for the event. A copy of the notification must be filed in the TMF and the ISF (as appropriate).

This notification should be reported:

- To the Sponsor by email pharmaco@abdn.ac.uk
- CTIMPs not submitted via combined review - to the MHRA by email clintrialhelpline@mhra.gov.uk marked 'Urgent Safety Measure' or as advised by MHRA when first discussing the USM. Also notify the REC who provided the favourable opinion for the trial by email marked 'Urgent Safety Measure'.
- CTIMPs submitted via combined review only – to the REC and MHRA in IRAS. No additional notification is required to the REC.
- Non-CTIMPs only: To the REC who provided the favourable opinion for the trial by email marked 'Urgent Safety Measure'.
- To relevant NHS R&D offices (email or hard copy) marked 'Urgent Safety Measure'.

3.6 The CI must then submit a Notification of a substantial amendment (amendment form, any updated document(s) including the USM changes agreed with the medical assessor) to the REC and MHRA within **2 weeks** of initial notification.

4. Abbreviations and definitions

Abbreviations

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
IMP	Investigational Medicinal Product
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
R&D	Research and Development (NHS)
REC	Research Ethics Committee
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Master File
USM	Urgent Safety Measure

Definitions

An Urgent Safety Measure is a procedure, which deviates from the approved protocol that is put in place when a research participant is identified as being at risk of harm in relation to their involvement in a research project and urgent action is required to manage the event and protect the participant.

An Urgent Safety Measure does not have prior approval from REC, MHRA or the Sponsor.

Urgent Safety Measures must be reported to REC, MHRA and Sponsor immediately after they are implemented.

5. Related documentation and references

SOP-QA-19	Amendments
SOP-QA-22	Adverse Events in CTIMPs
SOP-QA-39	Adverse Events in Medical Device Clinical Investigations
TMP-QA-51	Log of Breaches and Urgent Safety Measures