

SOP-QA-42 V3	
Title: Urgent Safety Measures	
Effective Date: 28-04-26	Review Date: 28-04-29
Author: Louise King, Research Governance Manager	
QA Approval: Richard Cowie, QA Manager	
Approver: Prof Seshadri Vasam, R&D Director	
Approver: Prof David Blackburn, Head of School	



GRAMPIAN CLINICAL RESEARCH OFFICE



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
3	Updated USM reporting requirements at 3.2, 3.3 and 3.5 Updated terminology at 3.5 Updated definitions at 4.0	28-04-26

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 licensing authority and substantial amendment submitted.

3. Procedure

Reporting of Urgent Safety Measures to Sponsor, REC and licensing authority (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 licensing authority. This shall be reported to the Sponsor **immediately** by email to pharmaco@abdn.ac.uk.

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Key to symbols  = Important point to note  = Warning

3.2 CTIMPs:

Initial phone call


The CI and/or Sponsor, shall also contact and discuss the issue with the licensing authority through the Clinical Trials Helpline, by calling (+44) 020 3080 6456 ideally within 24 hours (**no later than three days**) of measures being taken.

Below is the information the licensing authority 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 details of the affected IMP(s), including name, class, dose and duration of dosing, and route of administration
- Nature of the safety concern and whether it has been reported as a SUSAR
- Details of the measures taken and the rationale for those actions
- The number of UK participants currently or previously receiving the IMP, and the number of UK and non-UK participants affected by the USM
- any actions taken as part of the USM in trial locations outside the UK or in a non-UK trial using the same IMP


Where this information is not available during the initial call it should be provided as soon as possible and **no later than seven days** from the measure being taken.

If it is not possible to report a USM to the licensing authority by phone please send an email to clintrialhelpline@mhra.gov.uk ideally within 24 hours (**no later than three days**) of taking urgent measures. The email should include contact details, the trials IRAS ID or EudraCT number, a description of the USM and an explanation as to why it was not reported via phone. The licensing authority will contact you and provide advice regarding further actions

 Failure to notify the licensing authority of the implementation of an USM for safety reasons may be considered a serious breach.

Written notification

 The CI and/or Sponsor must then provide written notification to the licensing authority and REC describing the events requiring action to be taken, and the measures taken in response to those events, including any additional actions requested by the licensing authority **within seven days** of the measures being taken.



 Where a disease is pandemic and/or is a serious risk (or potentially serious risk) to human health the written notification must be made **as soon as possible**.

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 licensing authority by email clintrialhelpline@mhra.gov.uk marked 'Urgent Safety Measure' or as advised by the licensing authority when first discussing the USM. Also notify the REC who provided the favourable opinion for the trial by email marked 'Urgent Safety Measure'.

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- CTIMPs submitted via combined review only should be submitted via IRAS. No additional notification is required to the REC.

- 3.3 Non-CTIMPs: The CI and/or Sponsor shall notify the REC who provided the favourable opinion for the trial by email marked 'Urgent Safety Measure' **within seven days** of the measure being taken. The email should explain that an USM has been taken and the reasons for the USM. A copy of the notification must be filed in the TMF and the ISF (as appropriate).
- 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 submit a Notification of a substantial modification (modification form, any updated document(s) including the USM changes agreed with the licensing authority) to the REC and MHRA **within two weeks** of initial notification via the normal processes.

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.

5. Related documentation and references

SOP-QA-19	Modifications
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

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