UNIVERSITY OF LEICESTER

# Research Governance Office Sponsorship Standard Operating Procedures

## Urgent Safety Measures for Trials

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## 1.0 Introduction and Scope

The Medicines for Human Use (Clinical Trials) Regulations 2025 and ICH GCP E6(R3) set out specific requirements for reporting Urgent Safety Measures.

This Standard Operating Procedure (SOP) details the procedures to be followed when Urgent Safety Measures (USMs) are required to protect trial participants against any immediate hazard to their health and/or safety.

This SOP applies to any research (referred to as 'trials' hereafter) sponsored by the UoL.

## 2.0 Procedure

Once trial participants have been recruited, appropriate USMs may be taken at any time by the Sponsor and/or Investigator. Prior approval from the Medicines and Healthcare products Regulatory Agency (MHRA), Research Ethics Committee (REC) or Health Research Authority (HRA) is not required before implementing such actions.

Upon implementation of an USMs the Investigator (CI) or delegate must ensure the following are notified;

- Research Governance Office (RGO; where the USM was not implemented by the Sponsor)
- Chief Investigator (all trials)
- MHRA (for Clinical Trials of Investigational Medicinal Products (CTIMPs) and device trials)
- REC (all trials)
- Relevant Research & Development/Innovation (R&D/I) departments/trial teams/participants

Specific instructions for notifying each regulatory body can be found below, however, **individuals must refer to the MHRA and HRA websites to ensure up to date details for USM reporting are followed.**

rgosponsor@le.ac.uk must be copied into all email communication.

### 2.1 Notifying the Research Governance Office

The Investigator (or delegate) must;

1. Notify the RGO via rgosponsor@le.ac.uk immediately and within 24 hours.
2. Keep the RGO informed of the progress, outcome or resolution of the actions taken by sending follow-up information immediately and within 24 hours.
3. Contemporaneously complete the (Appendix 1) to provide a full and comprehensive record of all actions taken and the outcome.
4. Finalise, sign and file the USM Reporting Form in the TMF and ISF (where applicable), along with all supporting correspondence and documentation once the event is resolved.
5. Provide a copy of the signed form (and supporting documents) to RGO.

**Note:** Any action taken as a result of an USM must first be discussed with the Sponsor before notifying regulatory authorities, the local R&D department, other site teams and research participants. However, if the Sponsor does not respond promptly, this must not delay the required reporting to the parties listed in sections 2.2–2.6.

### 2.2 Notifying the Competent Authority

In the UK, the MHRA is the Competent Authority (also known as the licensing authority). Where other Competent Authorities are involved, the relevant website(s) must be consulted.

The Investigator (or delegate) must;

1. Notify the MHRA via the Clinical Trials Helpline on 020 3080 6456 **no later than 3 days (but ideally within 24 hours) of implementing the USM**. The information required for this notification is outlined on the MHRA website. A record of the conversation should be documented in Appendix 1.
2. Provide written notification to the MHRA **within 7 days of implementing the USM**. This is required regardless of the outcome of the telephone call. The information required for this notification is outlined on the MHRA website. Section 3 and 5 of Appendix 1 may be used to support this notification.
3. Respond to any additional requests for further information from the MHRA. Requests for additional information may be made either via email or IRAS depending on the route of notification as detailed below. Once the MHRA has received sufficient information, it will determine whether the measure taken was a USM and will communicate the outcome via the mechanisms listed above.

**For CTIMPs not submitted via combined review,** the notification to the MHRA should be sent by email to clintrialhelpline@mhra.gov.uk. A separate notification to the REC is also required as outlined in section 2.3.

**For CTIMPs submitted through combined review,** the USM notification should be submitted directly in IRAS. No additional notification to the REC is required.

The following link directs you to a flowchart created by the MHRA that illustrates the process.

### 2.3 Notifying the REC

The Investigator (or delegate) must;

1. Notify the REC **via email as soon as possible and within 7 days of implementing the USM**. The information required for this notification is outlined on the HRA website. The information should be provided to the REC that originally approved the trial using the appropriate (CTIMP or non-CTIMP) REC safety reporting cover sheet.

Section 3 and 5 of Appendix 1 may be used to support this notification.

### 2.4 Notification of trial locations in Multi-site trials

The CI (or delegate) must;

1. Notify the Principal Investigator (PI) at all research locations via email of the USM immediately and within 3 days of implementing the USM. The notification must clearly outline the specific actions to be taken.
2. Each PI must acknowledge receipt and confirm implementation of the USM by replying to the CI or delegate within 3 days of receiving notification.
3. The PI is responsible for informing their local R&D/I office, research team and any other applicable support departments e.g. pharmacy, in accordance with local policies and procedures.

### 2.5 Notifying Trial Participants

Trial participants must be informed of the USM and given the option to continue in the trial with the modified procedures (refer to section 3) or to withdraw from the trial.

Trial participants may be contacted initially by phone and then informed in writing of the rationale for the USM and the steps taken, or new procedures required, to minimise the risk. Participants who agree to remain in the trial must provide renewed consent.

A full record of all communication with participants must be documented in the participant medical notes, USM Reporting Form (Appendix 1), and where applicable, in the Case Report Form.

## 3.0 Submitting a modification is response to an USM

Where a USM requires a substantial modification, this must be submitted as soon as possible, and for CTIMPs, within two weeks of the initial telephone notification to the MHRA. No additional changes can be included in the modification.

### 3.1 For non-CTIMPs and trials not submitted via combined review

The modification should be marked as being in response to a USM and a copy of the USM notification should be submitted.

### 3.2 For trials submitted via combined review

The modification should be marked as being in response to a USM.

## 4.0 Temporary Halt

In some instances, it may be necessary to halt a trial. A temporary halt can apply to:

- The whole trial
- A specific aspect of a trial (e.g., new recruitment)
- Individual research location(s)
- All UoL Sponsored trials using the same IMP; and can halt recruitment and/or interrupt treatments of active participants.

The CI (or delegate) must notify the REC, MHRA and R&D/I offices of the temporary halt **immediately and within 15 days** from the date the trial is temporarily halted. The notification should be made as a substantial modification and should clearly detail the reason(s) for the temporary halt.

When there is evidence to suggest the trial is safe to recommence, a request to restart the trial, alongside the supporting evidence, should be submitted as another substantial modification. Should the Sponsor or Investigator decide the trial will not recommence after a temporary halt, the CI (or delegate) must notify the REC, MHRA and R&D/I offices **immediately and within 15 days** of the decision using the 'end of trial' declaration form.

## 5.0 Development Record

The table below summarises the revisions introduced in this version. Full historical change records are available within archived SOP versions.

| Date | Version number | Description of changes |
|---|---|---|
| April 2026 | 5.0 | • Removal of Office Address<br>• Change to reporting timelines as per updated regulations<br>• Revision of content to avoid repetition and aid clarity<br>• Updating wording to reflect terminology changes<br>• Removal of USM examples<br>• Removal of responsibilities table as responsibilities are laid out within the body of the SOP.<br>• Removal of full historical SOP review record; only the latest approved revision is now displayed, with prior versions retained in the document archive. |