SOP Number **010**

SOP Title **Urgent Safety Measures**

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1. PURPOSE

The purpose of this SOP is to describe the procedure to be followed when a clinical research study needs to be urgently amended or halted for reasons related to participant safety.

2. INTRODUCTION

During the course of a clinical study, new information or unexpected events which are likely to seriously affect the benefit-risk balance of the study may necessitate an immediate urgent change in the study procedures or a temporary halt to the study, in order to protect the health and safety of the participants. They do not need prior approval or authorisation before being implemented. However there must be notification to the appropriate bodies within the required timelines followed by a request for a substantial amendment.

3. SCOPE

The scope of this procedure is for all CTIMPs and device trials sponsored by the University of Oxford, but may also be used for other clinical research studies at the discretion of the unit.

4. DEFINITIONS

Urgent Safety Measure (USM)

An urgent safety measure is a substantial amendment to the conduct of the study, due to new information or an unexpected event which is likely to seriously affect the benefit-risk balance, which must be implemented immediately to protect the participants without needing to gain prior authorisation by the REC and competent authorities (MHRA in the UK - where study requires competent authority approval). Such safety measures may include a temporary halt to the study.

5. RESPONSIBILITIES

Study Team

All members of the study team are responsible for monitoring participant safety and must notify the CI immediately they become aware of any issue that may be a hazard to the health or safety of study participants.

Chief Investigator (CI)

The CI is responsible for identifying the requirement for an urgent safety measure and ensuring site awareness and immediate implementation. The CI is also responsible for reporting of the measure to host organisations, the competent authorities, the REC, and the Sponsor, within the required timelines. The CI is also responsible for preparation, quality review and submission of a substantial amendment following the implementation of the urgent safety measure.

Sponsor

The Sponsor is responsible for ensuring that urgent safety measures are reported by the CI to the REC and competent authority (MHRA in UK), if applicable, and authorising any subsequent substantial amendment.

6. SPECIFIC PROCEDURE

6.1 Awareness of Immediate Hazard to Participant Health or Safety

On becoming aware of an issue which poses an immediate threat to the health or safety of study participants, staff must immediately notify the CI.

6.2 Immediate Action

The CI must decide whether an urgent safety measure is required. The CI must also effectively communicate the required action to the sites, for immediate implementation. Acknowledgement of receipt of notification by the sites should be obtained.

The measures taken should be discussed by phone with a safety scientist at the competent authority (such as the MHRA) and the REC which issued favourable ethical opinion, ideally within 24 hours and in any event no later than 3 days from the date the measures are taken. The initial notification to the REC should be by phone with notice in writing sent within 3 days, and the competent authority notified according to their requirements.

6.3 Follow-up Action

The CI will submit formal written notification to the competent authorities (where applicable), REC and Sponsor within 3 days of implementation of the measure. Notification will include a covering letter outlining measures taken, the reasons for the measures, and the plan for further action. A substantial amendment should be submitted according to local regulations (for the MHRA, this is within approximately 2 weeks unless otherwise agreed).

Should a temporary halt result in a decision not to recommence the study, all the relevant parties must be notified of early termination within 15 days of the decision.

7. RELATED DOCUMENTS

University of Oxford Core SOP 011 – Applications, Amendments and Reporting

8. REFERENCES

Medicines for Human Use (Clinical Trials) Regulations 2004 (and subsequent amendments)

Health Research Authority: http://www.hra.nhs.uk/research-community/during-your-research-project/safety-reporting/

MHRA: https://www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues#report-an-urgent-safety-issue

9. CHANGE HISTORY

Version No.	Effective Date	Significant Changes	Previous Version No.
1.0	01 Jan 2014	First version of SOP	n/a
2.0	01 Jan 2017	Minor changes to clarify the definition of a Urgent Safety Measure and update website links.	1.0
3.0	See page 1	Minor clarifications to specific procedure, change of scope in light of SOP template update, update of Authoriser title.	2.0