Document Title: Urgent Safety Measures

Document Number: PTUC SOP071

Staff involved in development: *Job titles only*	Senior R&D Manager, R&D Operational Manager, Clinical Project Managers
Document author/owner:	Senior R&D Manager
Directorate:	Research and Development
Department:	Research and Development
For use by:	NHS Staff Trust-Wide
Review due:	July 2023

Summary of Amendments

Version Number	Modification:
Version 3.0	Minor procedural changes throughout

Key Points of this Document

- This document sets out the procedures to be followed by all Royal Papworth staff who are involved in clinical trials
- It provides guidance on how to report urgent safety measures that occur in the course of research studies to ensure compliance with the Trust's policies.

1 Purpose and Contents

a. This document defines the Trust's procedures for reporting and implementing Urgent Safety Measures for a clinical trial that is either managed by Royal Papworth Trials Unit Collaboration, or sponsored by Royal Papworth Hospital NHS Foundation Trust.

b. An Urgent Safety Measure is defined as a safety issue which is identified during a clinical trial which has immediate threat to the health and safety of trial participants.

2 Roles & Responsibilities

a. This Policy applies to all personnel that are conducting research at the Trust.

b. Staff involved in clinical trials must comply with the requirements set out in section 4.

c. It is the responsibility of the department's personnel to ensure that they are familiar with and adhere to all current SOPs, and have signed the relevant log in their training record.

d. The Chief Investigator (CI) has the responsibility to take appropriate urgent safety measures.

e. All members of the research team are responsible for reporting to the sponsor or delegated party, if they believe that the implementation of a safety measure is required.

3 Policy

a. This SOP is mandatory and, as per the Trust's Information Governance and Records Management framework, non-compliance with may result in disciplinary procedures.

4 Procedure

a. An **Urgent Safety Measure** (USM) is a procedure which is not defined by the protocol that can be put in place with immediate effect without needing to gain prior authorisation by the REC (and MHRA where applicable), in order to protect **clinical trial** participants from any immediate hazard to their health

b. Where the sponsor or investigator takes urgent safety measures to protect the safety of the research participants against any immediate hazard to their health or safety the

Research Ethics Committee (REC) and the Competent Authority (MHRA) must be informed immediately following implementation of the USM.

4.1 Informing the MHRA (CTIMPs/devices)

a. The Sponsor, CI or delegated individual should telephone the Clinical Trial Unit at the MHRA: for up to date contact numbers please access the following website: https://www.gov.uk/guidance/contact-mhra Contact with the MHRA and discussion of the issue with the safety scientist should take place immediately/within 24 hours of knowledge of the event. A medical assessor might contact the CI should further clarification be required. These conversations must be documented and filed in the Trial Master File.

b. The Sponsor or CI must submit a notice of substantial amendment to the MHRA within three days of implementation of the urgent safety measure. This notice must include:

1. Covering letter
2. The actions taken
3. The reason for the actions
4. The name of the safety scientist contacted in 4a
5. A notice of substantial amendment
6. Any supporting documentation

4.2 Informing the REC (all studies)

a. The Sponsor or CI must telephone the REC immediately. The REC is not required to approve urgent safety measures; however the committee will review urgent safety notifications to consider the appropriateness of the measures which have been implemented.

b. The Sponsor or CI must e-mail the REC within three days of implementation describing:

1. The actions taken
2. The reasons for the actions
3. The plan for further actions
4. Measures to be taken to inform trial participants (see section 4.5)

c. If the Chief Investigator takes urgent safety measures the Sponsor or the Sponsor's representative must be informed immediately by telephone.

4.3 Informing the Sponsor (Non Royal Papworth Sponsored Studies)

a. If the CI is based at Royal Papworth he/she must inform the Sponsor immediately and report the urgent safety measure in accordance with this SOP or the Sponsor's SOP.

4.4 Notifying participating sites and the research team (Royal Papworth Sponsored Studies)

a. The CI or delegate should inform all participating sites and Principal Investigators immediately of the implementation of the urgent safety measure and follow this up in writing/email within three days. An acknowledgment of receipt must be requested.

4.5 Notifying Trial Participants

a. The measures to be taken to inform trial participants must be detailed in the supporting documents sent to the Research Ethics Committee, who will review the appropriateness of the plans to contact participants.

b. The trial participants should be informed of the urgent safety measures and be given the option to either continue or withdraw from the trial. The participants should be informed in writing or as instructed by the Sponsor of:

1. The steps taken or new procedures required to minimise the risks
2. The rationale for the urgent safety measures
3. There may be a requirement to re-consent to an amended information and consent sheet

5 Risk Management / Liability / Monitoring & Audit

a. The R&D SOP Committee will ensure that this SOP and any future changes to this document are adequately disseminated.

b. The R&D Department will monitor adherence to this SOP via the routine audit and monitoring of individual clinical trials and the Trust's auditors will monitor this SOP as part of their audit of Research Governance. From time to time, the SOP may also be inspected by external regulatory agencies (e.g. Care Quality Commission, Medicines and Healthcare Regulatory Agency).

c. In exceptional circumstances it might be necessary to deviate from this SOP for which written approval of the Senior R&D Manager should be gained before any action is taken.

SOP deviations should be recorded including details of alternative procedures followed and filed in the Investigator and Sponsor Master File.

d. The Research and Development Directorate is responsible for the ratification of this procedure.

PTUC SOP071: Urgent Safety Measures
Further Document Information

Approved by: *Managment/Clinical Directorate Group*	Research and Development Directorate
Approval date: *(this version)*	Current active version approved date
Ratified by Board of Directors/ Committee of the Board of Directors:	STET
Date:	N/A
This document supports: *Standards and legislation*	Medicines for Human Use (Clinical Trials) Regulations 2004 and all associated amendments. UK Policy Framework for Health and Social Care Research (2018)
Key related documents:	Trust Research Policy

Equality Impact Assessment: Does this document impact on any of the following groups? If YES, state positive or negative, complete Equality Impact Assessment Form available in Disability Equality Scheme document DN192 and attach.

Groups	Disability	Race	Gender	Age	Sexual orientation	Religious & belief	Other
Yes/No	NO	NO	NO	NO	NO	NO	NO
Positive/Negative							

Review date:	July 2023

I certify the contents of this SOP has been reviewed and ratified

..... 4th August 2020.

Signed by Dr Ian Smith, Clinical Director of R&D — Date

SOP release date: 19th August 2020