York and Scarborough Teaching Hospitals Foundation Trust R&D Unit Standard Operating Procedure R&D/S12

Receiving and Acknowledging Safety Notifications to the R&D unit

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

SOP Reference:	R&D/S12
Version Number:	5.0
Author:	Jonathan Hawker
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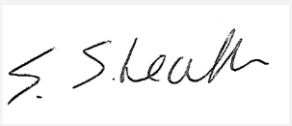
Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	
	Date:	8th November 2022
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	
	Date:	8th November 2022

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Details of significant changes
1.0	10th September 2009	
2.0	24th October 2011	Clarification over term 'Alliance Trust' and minor modification to ensure applicability to non-CTIMP studies also.
3.0	17th March 2014	Removal of references to the North and East Yorkshire R&D Alliance. Change of fax number. Minor changes to procedure for receiving faxes to the R&D unit. Clarification of primary contacts in the event of safety notification.
4.0	15th August 2017	
5.0		Change of link to R&D website. Change of Trust name. Removed reference to faxing notifications. Included Trial Managers in section 4.3.
6.0	6th December 2022	General changes made to fit in with current R&D structure. Removed all remaining references to faxing.

Contents

1 Introduction, Background and Purpose

This SOP outlines how notification of the following reports made to the R&D Unit will be received and acknowledged:

- Serious Adverse Event (SAE)/Serious Adverse Reaction (SAR)/Suspected Unexpected Serious Adverse Reaction (SUSAR) for **Trust Sponsored studies**
- Serious Adverse Reactions (SAR)/ Suspected Unexpected Serious Adverse Reaction (SUSAR) **for hosted studies**
- Suspected Serious Breach for all studies
- Urgent Safety Measure **for all studies**

Collectively the above reports that notify the Sponsor of safety issues with studies are referred to as 'safety notifications' for the purpose of R&D Unit SOPs.

Where the Trust is sponsoring a research study, the research team ***must*** follow the SOP/S19 & S05 for research related adverse event reporting.

Where the Trust is hosting a research study, the research team should follow the Sponsor's instructions for reporting safety events. However, the Investigator ***must*** also notify the R&D Unit immediately (within 24h) by email to research.governance@york.nhs.uk when an SAE deemed as *possibly, probably or definitely* related is reported. Any such events can be further confirmed as SAR or SUSAR and must be closely monitored by the R&D Unit.

Equally, all breaches suspected or confirmed as serious and all urgent safety measures must be notified to research.governance@york.nhs.uk within 24h from becoming aware of them, and must immediately be assessed and closely monitored by the R&D Unit.

2 Who Should Use This SOP

This SOP should be used by all members of the R&D Unit.

3 When this SOP Should be Used

This SOP should be followed by members of the R&D Unit upon receipt of notification of (i) an SAE/SAR/SUSAR, (ii) a suspected Serious Breach of GCP or the trial protocol, or (iii) implementation of Urgent Safety Measures. The purpose is to ensure that all safety notifications reported to the R&D Unit are collected and acted upon within the specified timescales.

4 Procedure(s) for Sponsored Studies

For definitions of (i) Adverse Events and Adverse Reactions arising from clinical research, (ii) Serious Breach of GCP or the trial protocol, (iii) Urgent Safety Measures, refer to the SOPs listed in section 6.

4.1 Notification to R&D Unit

Safety notifications must be made to the R&D Unit using the appropriate form sent by email. Teams must NOT bring safety notifications to the R&D Unit and leave them with a member of staff, nor must they be sent by email to a named member of the R&D Unit in case that individual is absent from the office.

All reports must therefore be emailed to research.governance@york.nhs.uk.

The **Research Governance mailbox** should be used for notifications of:

(i) SAEs/SARs/SUSARs **for Trust sponsored studies**
(ii) SARs/SUSARs **for hosted studies**
(iii) Suspected Serious Breaches of GCP or the trial protocol **for all studies**
(iv) Urgent Safety Measures **for all studies**

It is the responsibility of the Unit Administrator(s) to check the Research Governance mailbox every working day and to act immediately upon receipt of any safety notification. In the event of absence of the R&D Unit Administrators then the R&D Unit Operations and QA staff have a responsibility to check the Research Governance mailbox.

On receipt of a safety notification reported by email, the Unit Administrators (or other designated individual) will immediately contact the appropriate individual responsible for dealing with safety notifications and request their acknowledgment of receipt (see details in section 4.3). Should the acknowledgment of receipt not come back by 4pm on the day, the Senior Manager on duty should be informed.
Under no circumstances should any safety notifications received be printed and left on staff desks.

It is a requirement that the R&D Unit research.governance mailbox is checked every working day. On any occasion when the R&D Unit Administrators are absent from work then this must be checked by other appropriately identified a member of the R&D team.

4.2 Other forms of notification to the R&D Unit

Should a member of the R&D Unit receive either formal or informal notification via personal email, in writing or in person, then they should immediately contact the appropriate individual responsible for dealing with the safety notification. Refer to details in section 4.3.

4.3 R&D Unit contact personnel

The individual named below (or designated other) will be responsible for ensuring that acknowledgement of receipt of the safety notification is sent to the reporting investigator as soon as possible and before noon of the following working day. The acknowledgement should be sent to the email address from which the report was sent unless an alternative arrangement has been agreed in writing with the research team.

- SAE/SAR/SUSARs: Upon receipt of notification to the R&D Unit, the Research Quality Assurance Manager (QAM) or Research Quality Assurance Co-ordinator (RQAC) or other designated individual will

follow the procedures as outlined in the R&D SAE/SUSAR Handling Process SOP (R&D/S13) immediately upon learning of the event.

- Serious Breach of GCP or the Trial Protocol: Upon receipt of notification of a suspected Serious Breach to the R&D Unit, the Research Quality Assurance Manager (QAM) or Research Quality Assurance Co-ordinator (RQAC), or other designated individual will immediately follow the procedures as outlined in the Serious Breach of GCP or the Trial Protocol (R&D/S04). Upon learning of the event and carrying on initial assessments, they will notify the Research Adviser or the Senior Manager on duty.

- Urgent Safety Measure: Upon receipt of notification of an Urgent Safety Measure, the Research Quality Assurance Manager (QAM) or Research Quality Assurance Co-ordinator (RQAC), or other designated individua will immediately follow the procedures as outlined in the Urgent Safety Measure SOP (R&D/68). Upon learning of the event and carrying on initial assessments, they will notify Research Adviser or the Senior Manager on duty .

For clarity, the date of notification to the R&D Unit will be designated as 'day 0' of the reporting period. This is regardless of when R&D Unit personnel act upon the notification.

4.4 Retention of documentation

The safety notification and all subsequent information and correspondence pertaining to the safety notification will be saved on X drive in the 'Research QA' Folder, and records maintained up to date until the matter is fully resolved.

In addition, electronic copies of key correspondence should be saved into an appropriate e-ISF held on the Q drive, hard copy ISF and on Edge.

5 Related SOPs and Documents

R&D/S04 Breaches of GCP or the Study Protocol

R&D/S05 Research Related Adverse Event Reporting Procedure for CTIMPs Studies (Including reporting a Pregnancy)

R&D/S13 R&D SAE/SUSAR Handling Procedure for Sponsored CTIMPs

R&D/S19 Research Related Adverse Event Reporting for non-CTIMP Studies

R&D/S68 Urgent Safety Measures or Safety Concerns requiring a temporary or permanent halt to the study