York 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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.northyorksresearch.nhs.uk/sops.html and/or Q-Pulse

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Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Signature:	Signed copy held by R&D Unit
	Date:	13th July 2017
	Name/Position:	Sarah Sheath, SOP Controller
	Signature:	Signed copy held by R&D Unit
	Date:	13th July 2017

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	

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)/Suspected Unexpected Serious Adverse Reaction (SUSAR)
- Suspected Serious Breach
- Urgent Safety Measure

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.

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/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 fax. All other forms of notification to the R&D Unit should be strongly discouraged unless they have been agreed in advance with the R&D Unit. 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 faxed to the main R&D fax number or (as a second option where fax is not available to a team) emailed to research.governance@york.nhs.uk.

The R&D Unit fax (01904 725700) is used for receiving notification of:

(i) SAE/SUSARs
(ii) Suspected Serious Breaches of GCP or the trial protocol
(iii) Urgent Safety Measures

It is the responsibility of the Unit Administrator(s) to check the fax and research.governance mailbox every working day and to act immediately upon receipt of any safety notification. If the Unit Administrator is absent

from the office then it is the responsibility of the Administrative Co-ordinator to check the fax and email mailbox. In the event of absence of the R&D Unit personnel named above then all R&D Unit staff have a responsibility to check the fax and research.governance mailbox. The individual who checked the fax mailbox must, upon doing so, sign their name on the fax log retained in the R&D admin office.

On receipt of a safety notification reported by fax or email, the Unit Administrator (or other designated individual) will immediately contact the appropriate individual responsible for dealing with the safety notification received. See details in section 4.3.

Under no circumstances should any safety notifications received be printed and left in an individual's pigeon hole or on their desk. Faxed or emailed notifications should not be forwarded to another individual's email inbox without first contacting that individual.

It is a requirement that the R&D Unit fax and research.governance mailbox is checked every working day. On any occasion when the R&D Unit may be unstaffed then these will be checked remotely by the Research Adviser.

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 fax number or email address from which the report was sent unless an alternative arrangement has been agreed in writing with the research team.

- SAE/SUSARs: Upon receipt of notification of an SAE/SUSAR to the R&D Unit, the Research Quality Assurance Manager (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 Adviser (or other designated individual) will immediately notify the Head of R&D and the Research Quality Assurance Manager. The Research Adviser (or designated other) will follow the procedures as outlined in the Serious Breach of GCP or the Trial Protocol (R&D/S04) immediately upon learning of the event.

- Urgent Safety Measure: Upon receipt of notification of an Urgent Safety Measure, the Research Adviser (or other designated individual) will

immediately notify the Head of R&D and Research Quality Assurance Manager. A Research Adviser (or designated other will follow the procedures as outlined in the Urgent Safety Measure SOP (R&D/68) immediately upon learning of the event.

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 printed immediately upon receipt and a printed copy retained in the *Holding File* located in the R&D Unit until the matter is fully resolved. Copies of all information will then be placed in the Sponsor file (or R&D File where the Trust is not the Sponsor) and archived at the end of the study.

In addition, electronic copies should be saved into an appropriate folder within in the study project folder held on the X drive.

5 Notification of suspected SUSARs or suspected Serious Breaches for 'hosted' Studies

Where the Trust is hosting a research study, the research team should follow the Sponsor's instructions for reporting serious adverse events or suspected serious breaches. However the Investigator ***must*** also notify the R&D Unit immediately by efax (01904 725700) or email to research.governance@york.nhs.uk.

On receipt of such a notification, the Research Adviser, or Head of R&D (or other designated individual) will liaise closely with the Investigator to ensure that the necessary action is taken.

All documentation and correspondence will be printed and held in the R&D Unit 'holding file' until the matter is considered 'closed' whereupon the documentation will be moved to the R&D File with an additional copy retained in the Unit's central 'Oversight' file.

In addition, electronic copies should be saved into an appropriate folder within in the study project folder held on the X drive.

6 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