York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
SOP
R&D/S112

Research Related Adverse Incident Reporting

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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Author:	Monica Haritakis
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Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Date:	17th January 2023
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	17th January 2023

This SOP will normally be reviewed at least 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	Reviewers	Details of significant changes
1.0	14th February 2023	Monica Haritakis Jonathan Hawker Kate Howard Paul Brittain	

Contents

1 Introduction, Background and Purpose

In the same way that adverse incidents, including clinical, non-clinical and near misses can involve patients, staff and visitors during routine care, adverse incidents can also occur during research related activities. It is important that research related adverse incidents are treated in the same way as non-research related adverse incidents. Research related Adverse Incidents (AIs) must therefore be reported in accordance with the hosting Trust's own Adverse Incident Reporting Procedure/System.

All staff have a responsibility to report incidents in accordance with the procedures outlined in the Trust's AIRS policy. Staff must ensure that all adverse incidents and near misses affecting staff, patients, visitors, and contractors are reported via online AIRS forms.

2 Who Should Use This SOP

All members of the Research and Development team involved in reporting and reviewing AIs.

3 When this SOP Should be Used

This SOP should be used when a member of staff is involved in or witnesses an adverse incident, or a near miss incident that occurred on a research study/ involves a research participant within the Trust.

4 Procedure(s)

4.1 What should be reported as an adverse incident, or a near miss incident

Research staff must ensure that the following incidents are submitted via a DATIX report, highlighted via the AIRS system and fed into the relevant Directorates, and risks escalated to the research study CI/PI and relevant clinicians:

- failure to adhere to departmental procedures;
- failure to follow research protocols/SOP/manuals;
- any medication related issues (including IMPs and non-IMPs) or study treatment/study procedures related issues.

4.2 Reporting an adverse incident, or a near miss incident that occurred on a research study/ involves a research participant

If an individual is involved in or witnesses an adverse incident, or a near miss incident that occurred on a research study or involves a research participant within the Trust, they must ensure that an electronic AIRS form is completed promptly and reported to their Manager or most senior person on duty as

appropriate. It may also be appropriate for the study PI and study Sponsor to be notified of the incident.

Research related AIRS forms must be submitted with the following question confirmed as 'yes': *Did the incident occur during a research study?* This will ensure R&D is notified about all AIs that occurred on a research study/ involved research participant (for List of AIRS/Datix Categories please see Appendix 17 of the AIRS Policy).

The reporting individual must check if the reported AI meets the criteria for an AE/SAE/SAR (study specific criteria).

Please note: all SARs/SUSARs must be reported within 24hrs to the study sponsor & R&D Unit as per SOP/S19 & S05.

The reporting individual and the incident reviewer must check if the reported AI meets the criteria of a suspected serious breach.

Please note: any suspected serious breaches to study protocols must be reported within 24hrs to the study Sponsor and the R&D Unit as per SOP/S04.

The reporting individual must respond to queries from the handler/ reviewer promptly.

4.3 Investigating the Incident

A handler will be assigned to each DATIX by the individual reporting the incident.

Senior Research Nurses are responsible for ward-based/clinic-based nursing issues. All Senior Nurses are 'Handlers' on DATIX – they are to be assigned as handlers for all incidents form within their research speciality.

PIs/CIs and co-Investigators are responsible for investigating incidents involving research study Clinicians and Doctors in their Directorate.

The Research QA Manager is responsible for wider clinical research related issues across all specialties e.g. incidents affecting more than one specialty/ more than one research study.

The Research Advisor and Research QA Manager are responsible for any incidents related to Trust sponsored studies.

The Commercial Research Manager is responsible for any incidents involving research samples (receipt/labelling, handling, processing, storage, shipping).

The Pharmacy Clinical Trials Manager is responsible for any incidents involving medication/pharmacy (handling, storage, prescriptions, dispensing).

Where a member of the R&D team is the Handler they must:

- confirm that the individual is a research participant
- Review incident details

- Complete Investigation (root cause analysis)
- Assess & confirm severity & results
- Assign CAPA

Where the Handler **is not** a member of the R&D team the Research QA team must:

- Confirm that the individual is a research participant
- Review incident details
- Send communication & feedback as required
- Review outcomes & implement

For all AIs the individual reviewing should investigate whether the AI is also a suspected serious breach or an AE/SAE for the study. If the AI is deemed to be a suspected serious breach or an AE/SAE this should be recorded and reported as per the relevant SOP.

4.4 QA responsibilities

All AIs marked as 'occurred on a research study' are automatically sent to reseach.governance@york.nhs.uk & to the R&D QA Manager. For all AIs received the Research QA team will follow up via email with the assigned handler or the R&D QA Manager within 24 hours.

Once the incident has been 'closed' the QA team will download PDF report and save for R&D records.

The QA team will maintain a record of all AIs that occurred on a research study and periodically review, screen for pattern and trends. These will be reviewed at the quarterly QA meeting.

The Research QA team will regularly review the list of DATIX handlers.

5 Related SOPs and Documents

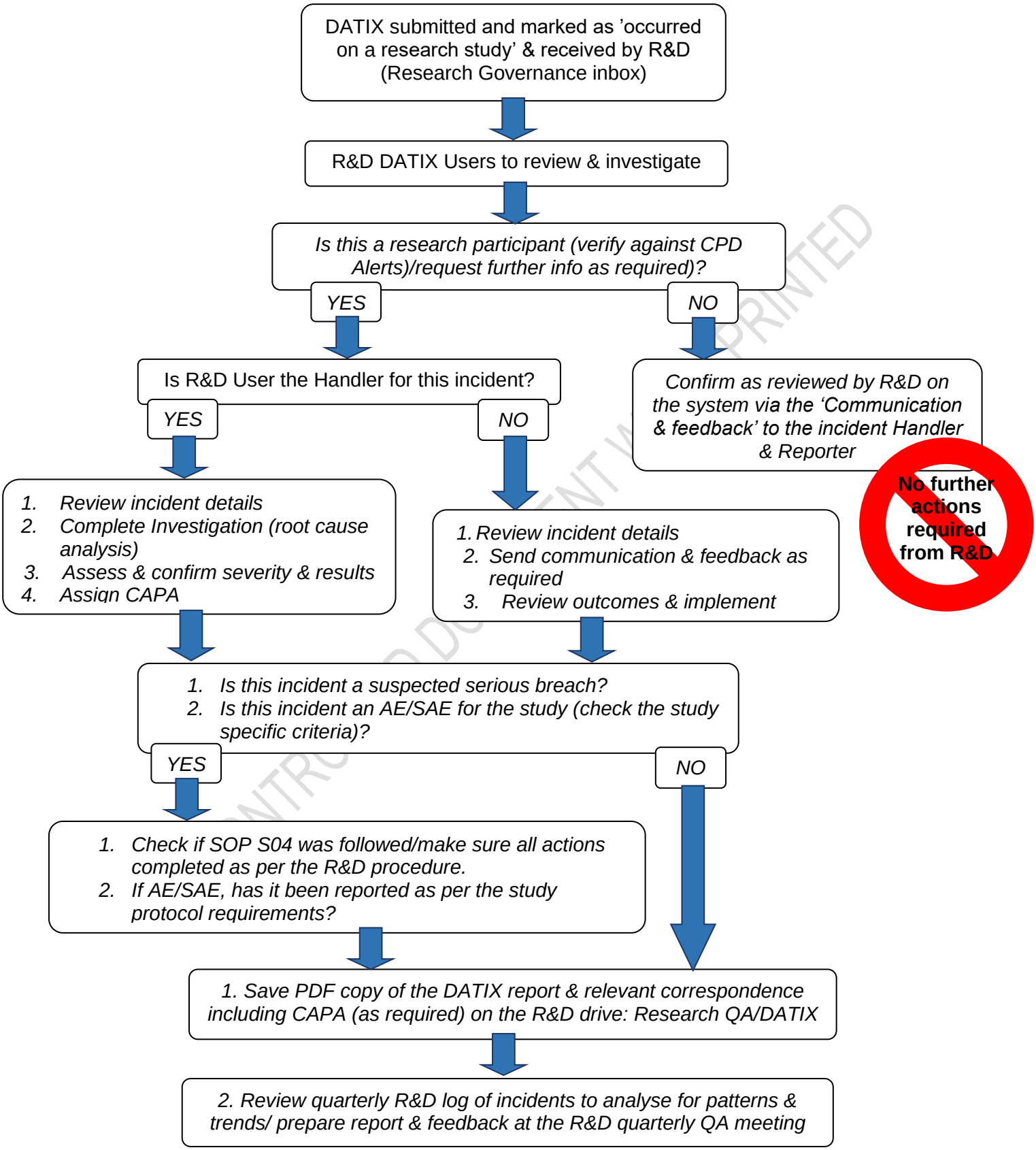
PATIENTSAFETY10 - Incident Management Policy (Incident Management Policy (formerly AIRs policy) — York NHS Staff Room (yha.com))

R&D/S04- Breaches od GCP or the Study Protocol

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

R&D/S05- Research Related Adverse Event Reporting Procedure for CTIMP Studies (including reporting of a pregnancy)

6 Appendix A


DATIX submitted and marked as 'occurred on a research study' & received by R&D (Research Governance inbox)
R&D DATIX Users to review & investigate
Is this a research participant (verify against CPD Alerts)/request further info as required)?
YES
NO
Is R&D User the Handler for this incident?
YES
NO
Confirm as reviewed by R&D on the system via the 'Communication & feedback' to the incident Handler & Reporter
No further actions required from R&D
1. Review incident details
2. Complete Investigation (root cause analysis)
3. Assess & confirm severity & results
4. Assign CAPA
1. Review incident details
2. Send communication & feedback as required
3. Review outcomes & implement
1. Is this incident a suspected serious breach?
2. Is this incident an AE/SAE for the study (check the study specific criteria)?
YES
NO
1. Check if SOP S04 was followed/make sure all actions completed as per the R&D procedure.
2. If AE/SAE, has it been reported as per the study protocol requirements?
1. Save PDF copy of the DATIX report & relevant correspondence including CAPA (as required) on the R&D drive: Research QA/DATIX
2. Review quarterly R&D log of incidents to analyse for patterns & trends/ prepare report & feedback at the R&D quarterly QA meeting