Dorset County Hospital NHS Foundation Trust

RESSOP011 - RESEARCH SAFETY REPORTING

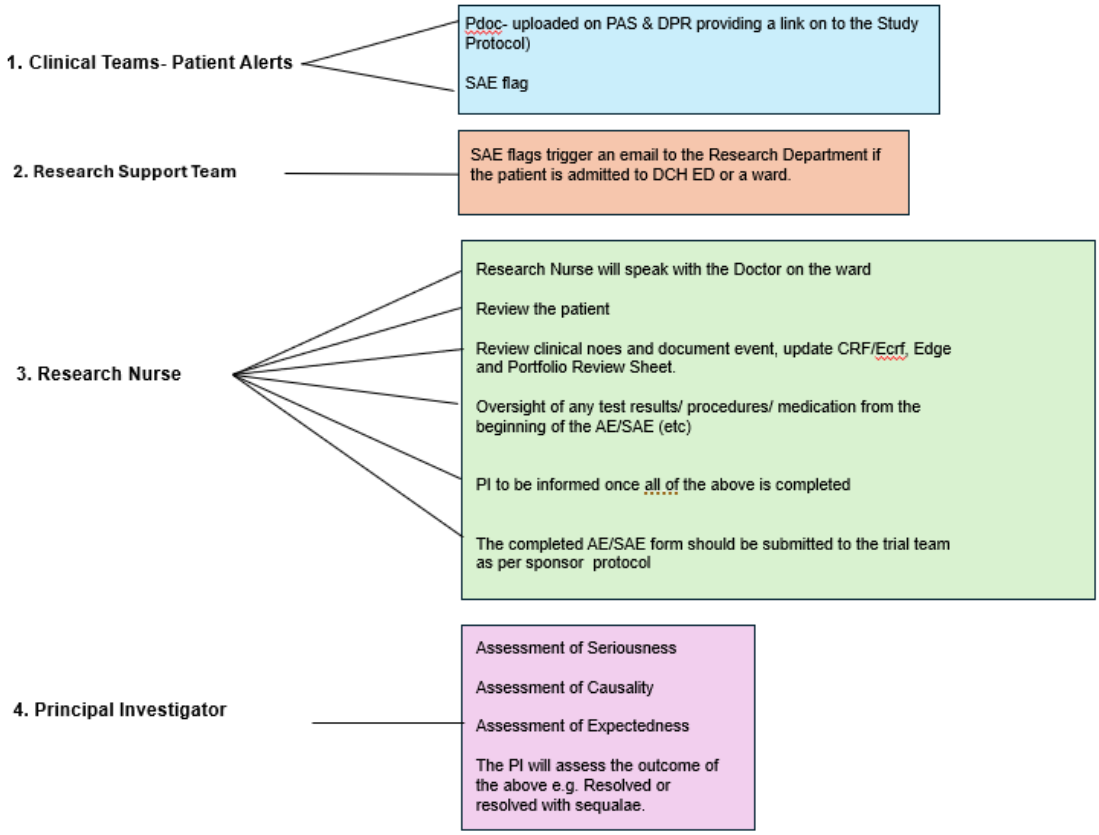
SOP Title	RESSOP005 - Research Safety Reporting		
SOP Number	**RESSOP005**	**Policy Version Number**	**2**
Applicable to	All Research staff with the delegation duty of completing safety reporting		
Aim of the Policy	The purpose of this Standard Operating Procedure (SOP) is to explain the local processes and requirements for reporting adverse and serious adverse events (AE & SAE) as well as Suspected Unexpected Serious Adverse Reactions (SUSAR), for both multicentre studies that DCH is taking part in and studies which are sponsored by DCH.		
Next Review Due Date	**11/02/2027**		
Author/ Reviewer	Dennise Hill Research Bank Nurse, Joanna Allison Lead Research Nurse and Anthony Homer Research Governance and Quality Lead		
Policy Sponsor	Sarah Doyle Joint Head of Research		
Responsible Executive	N/A – Local SOP		
Expert Group	Research Quality Working Group		
Date Approved	04/02/2025		
Ratified by	Sarah Doyle – Head of Research		
Date Ratified	19th February 2026		
Primary Specialty	Research		
Secondary Specialty	All departments currently active in Research		

Document Version Management			
Version	Date	Reviewer	Description of Change(s)
1.1	2024	Dennise Hill & Amy Thomson	Increase in department specific information/ Case studies added/ Expansion on abbreviation and description table

Content

Quick Reference Guide:

Here is the multi-disciplinary team oversight of the administration, roles and responsibilities and the process for safety reporting for all AEs/SAEs.
This information is in accordance with Dorset County Hospital policies as well as the Research Department SOPs with the involvement of Research Governance for quality assurance.



1. Introduction

a. ICH Good Clinical Practice guidelines require all adverse events (AE's) and serious adverse events (SAE's) experienced by research subjects to be documented and reported. It is important that this SOP is followed accurately and concisely, failure in complying with this document can result in regulatory approval being withdrawn from an individual project, or, in some extreme cases, from all research carried out by the Chief Investigator (CI) or Principal Investigator (PI).

2. Aims and Objectives of this SOP

a. The key aim of the Standard Operation Procedure (SOP) is to explain the local process and requirements for reporting Adverse and Serious Adverse Events as well as Suspected Unexpected Serious Adverse Reactions (SUSARS)/SAR/ DSUR for both multicentre studies that DCH is taking part in and studies which are sponsored by DCH.

3. Scope / who is the SOP for?

a. The SOP describes the actions to be taken by the DCH Research Department upon receiving notification of an Adverse Event, Serious Adverse Event (SAE) or Serious Adverse Reaction (SAR) or Suspected Unexpected Serious Adverse Reaction (SUSAR) for a sponsored research study.

b. This SOP is for all staff of the research department and trust-wide who are actively participating in research and are signed on the delegation log for documenting safety events.

4. Definitions

Acronyms	Definition	Description
AE	Adverse Event	"An undesired harmful effect that occurs during or after the use of a drug or other intervention but is not necessarily caused by it." Glossary | NIHR Evidence For example, an unfavourable and unintended sign, including an abnormal laboratory finding, symptoms or disease, including for example, a cold or an accident.
AR	Adverse Reaction	Any untoward and unintended responses to an investigational medicinal product related to any dose administered.
CI	Chief Investigator	The Investigator with overall responsibility for the research. In a multisite study, the CI has coordinating responsibility for research at all sites. The CI may also be the PI (Principal Investigator) at the site in which they work. In the case of a single-site study, the CI and the PI will normally be the same person.
CLTR	Clinical Trial	A 'flag' on PAS to identify that the patient is participating in a clinical trial.

CRF	Case Report Form	A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject. ICH GCP - 1. GLOSSARY
CTA	Clinical Trials Authorisation	The regulatory approval for a clinical trial of a medicinal product issued by the MHRA.
CTIMP	Clinical Trial of an Investigational Medicinal Product	A clinical trial that is within the scope of the UK Medicines for Human Use (Clinical Trials) Regulations 2004. An investigation in human subjects, other than a non-interventional trial, intended: a) to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products b) to identify any adverse reactions, or c) to study absorption, distribution, metabolism and excretion, with the object of ascertaining the safety and/or efficacy of those products. Glossary | Clinical Trials Toolkit
DATIX		An online system for NHS staff to report any incidents and risks within and across organisations/trusts.
DCH	Dorset County Hospital	About Us | Dorset County Hospital
DPR	Digital patient Record	A database for storing of patient medical records
DSMB	Data Safety Monitoring Board	Data and Safety Monitoring Board: An independent committee composed of clinical research experts and community representatives that reviews data whilst a clinical trial is in progress to ensure that participants are not being exposed to undue risk.
DSUR	Development Safety Update Report	Development Safety Update Report: In addition to the expedited reporting required for Suspected Unexpected Serious Adverse Reaction (SUSARs), Sponsors are required to submit a safety report (DSUR) to the Medicines and Healthcare products Regulatory Agency (MHRA) and Research Ethics Committee, once a year throughout the clinical trial or on request.
Ecrf	Electronic Case Report Form	An electronic equivalent of a CRF as above.
EMA	European Medicines Agency	The European Medicines Agency A body of the European Union which has responsibility for the protection and promotion of public health through the evaluation and supervision of medicines for human use.
EMEA	European Medicines Evaluation Agency	"The mission of the European Medicines Agency (EMA) is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health in the European Union (EU)". What we do | European Medicines Agency (EMA) (europa.eu)
EU	European Union	An international organisation comprising of 27 countries.
GCP	Good Clinical Practice	This is a set of internationally recognised ethical and scientific quality requirements that must be followed when designing, conducting, recording and reporting clinical trials that involve people, the latest version can be found on the HRA website Good Clinical Practice - Health Research Authority..
HRA	Health Research Authority	As part of the Research Ethics Service, HRA approval is required across the NHS as an assessment of governance and legal compliance.

ICH	International Conference for Harmonisation	A collaboration between regulators and the pharmaceutical industry in Europe, the United States and Japan to establish common standards for clinical trials. ICH GCP is a widely recognised standard for Good Clinical Practice in clinical trials. Clinical trials regulations reform - Health Research Authority
IMP	Investigational Medicinal Product	An unlicensed new drug, an existing drug tested outside its licence, or existing drugs tested against each other for their efficacy/safety. The Medicines and Healthcare products Regulatory Agency (MHRA) provide advice to help you decide if your product is an investigational medicinal product (IMP).
ISF	Investigator Site File	A file designed for use in organising and collating all Essential Documentation required to conduct a study in accordance with the principles of GCP and the applicable regulatory requirements (e.g. REC approval letter/correspondence, MHRA approval, blank CRF, staff CVs, delegation of duties log etc.)
MedDRA	Medical Dictionary for Regulatory Activities	A dictionary online developed by ICH to facilitate the availability of regulatory information internationally for any medical product used by humans.
MHRA	Medicines and Healthcare products Regulatory Agency	"The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK". About us - Medicines and Healthcare products Regulatory Agency - GOV.UK (www.gov.uk)
PI	Principal Investigator	The lead person at a single Site designated as taking responsibility within the research team for the conduct of the study. Responsible for all aspects of the study conduct at a Site.
REC	Research Ethics Committee	A Research Ethics Committee (REC) established in any part of the UK in accordance with GAfREC and/or recognised by the UKECA under the Clinical Trials Regulations. Research Ethics Service and Research Ethics Committees - Health Research Authority
RSI	Reference Safety Information	The RSI is used for determining the expectedness of a Serious Adverse Reaction (SAR). If the serious event is considered related to the IMP and the serious reaction is not included in the RSI, then this becomes a SUSAR and must be reported to the MHRA (and Research Ethics Committee for cases originating in the UK) as per statutory timelines. https://mhrainspectorate.blog.gov.uk/2021/02/05/reference-safety-information-rsi-for-clinical-trials-part-iii/
SAE SAR	Serious Adverse Event Serious Adverse Reaction	Serious Adverse Event (SAE). Serious Adverse Reaction Any AE, AR or UAR that any dose: • Results in death • Is life-threatening • Results in patient hospitalisation or prolongs existing hospitalisation. • Results in persistent or significant disability/incapacity. • Results in a congenital anomaly/birth defect. Serious Adverse Reaction for CTIMPs, an adverse reaction which also meets the definition of a serious adverse event." Source: Glossary of Terms - University of Birmingham

		An 'adverse reaction' is any untoward and unintended response which is likely related to the investigational medicinal product/medical device/intervention. Safety reporting - Health Research Authority
SOP	Standard Operating Procedure	Detailed written instructions designed to achieve uniformity of the performance of a specific function.
SUSAR	Suspected Unexpected Serious Adverse Reaction	Suspected Unexpected Serious Adverse Reaction. This is a SSAR which is also "unexpected", meaning that its nature and severity are not consistent with the information about the medicinal product in question set out: (a) in the case of a product. Safety reporting - Health Research Authority
TMF	Trial Master File	A file with Essential Documents held by the Chief Investigator/Sponsor organisation. The PI/Investigator Site File also forms part of the TMF.
UAR	Unexpected Adverse Reaction	For CTIMPs, an adverse reaction, the nature and severity of which is not consistent with the applicable product information (e.g. investigator's brochure or summary of produce characteristics for an authorised product) Glossary of Terms - University of Birmingham
USM	Urgent Safety Measures	A sponsor or investigator may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety, without prior authorisation from a regulatory body. Safety reporting - Health Research Authorityn
PAS	Patient Administration System	This is a computer software program which is used within healthcare organisations to track and manage patient information. It will record non-clinical patient details and is an integral part of managing patient engagement across many healthcare services. Patient Administration System (PAS) | Access Oceano
Pdoc	Patient document	A patient record which can contain information in any number of formats, in this case the Pdoc would be attached to an email which is sent to the research department, the core of a record is held in digital form.
PIS	Participant Information Sheet	The participant information sheet describes in lay (clear and easy) language a research project, explaining its purposes and methods, and outlining the risks and benefits of participation. Information sheets are also referred to as 'Patient Information Sheet'. Glossary of Terms - University of Birmingham

5. Equality Impact and Compliance Assessment

Equality has been considered, see Appendix 1.

6. Data Protection Impact Assessment

Data protection and confidentiality has been considered, see Appendix 2.

7. Stakeholders and Consultation

- Research Nursing, Midwifery and Clinical trials assistant staff at Dorset County Hospital
- Research Leadership Review at Dorset County Hospital.
- Research Quality Group at Dorset County Hospital.
- Research Management and Governance
- SOP Working Group Research Department DCH

8. Roles and Responsibilities

The policy applies to all staff of the research department, and those who have an active role in the study, when an AE/SAE or SUSAR/ SAR notification is received. The following 'key staff' also have the responsibilities listed here:

- Head of Department has the responsibility to implement the contents of the SOP across the department.
- Research Governance and Quality Lead has the responsibility to ensure that this document is accessible to all those who require it.
- All members of the Research Senior Leadership Team
- Author of this document has the responsibility to ensure that this document is relevant and up to date.
- Principal Investigator/s has the responsibility to ensure that these reporting requirements are met at their site.
- Chief Investigators have the responsibility of preparing and disseminating a written report of all serious adverse events to local research sites. Copies of this report are to be filed in the study file.
- The Research team has the responsibility to inform the organising body as soon as made aware of the Serious Adverse Event.
- Research Project Managers will have responsibility for escalating SAEs that they are aware of and recording SAEs as delegated by the clinical teams on the edge database.

9. Training and Implementation

- New users must read and understand this SOP before carrying out this procedure
- Existing users must read and understand the revisions section.
- All users must have undergone recent GCP training
- All users will have undergone mandatory training according to their individual job role as documented in their training matrix.
- Study Specific Training as per individual sponsor/ study team

10. Risk Management

Risk Management for this SOP is conducted via three key processes;

a. The SOP approval process involves governance and risk subject matter experts identifying generalized risks and mitigations to be written into the draft SOP prior to approval.

b. The delivery of this SOP will be monitored both by the review periods identified and the datix incident reporting system to implement corrective and preventative actions through this SOP.

c. The study feasibility process (RESSOP009) identifies risks related to individual study delivery and their compliance with this SOP.

11. Approval

a. This SOP has been approved by the Research Governance and Quality led as well as the Research Quality Group, in accordance with the Policy and Procedure for the Development and Management of Policies and Clinical Guidance (Ref 1126).

12. Monitoring and Reviewing Arrangements

Monitoring:

Monitoring of this procedure and SOP will take place in 1 year after submission the first instance, and then at least every three years, in accordance wth the Policy and Procedure for the Development and Management of Policies and Clinical Guidance (Ref 1126).

13. Dissemination

a. This approved SOP will be made available on the Florence database and published and accessible via the Trust website.

14 Policy Content

In this section, we focus on describing AEs and SAEs in detail, how they are dealt with by the Research and Clinical teams, who is responsible for the reporting of them and assessing the seriousness, causality and expectedness. It is important to note, that the procedures for safety reporting will vary depending on type of study and this is further explained in this section.

All Adverse Events can be classified into different categories these are as follows:

1. Adverse Events
2. Adverse Reaction
3. Serious Adverse Event/Reaction
4. Suspected Serious Adverse Reaction
5. Suspected Unexpected Serious Adverse Reaction

Each of these forms of AEs are subject to a different format of reporting them, this is detailed further below. In order to assess whether an Adverse Event is classified as an AE or and SAE the following procedure should be followed: To complete the assessment of an AE and SAE, the PI will cover the following 3 areas: Seriousness, Causality and Expectedness. In the event of the PI being unavailable at the time of the AE/SAE being initiated, the research nurse will submit an initial AE/SAE form to the trial team (without the 3-step assessment). In some cases, the sponsor protocols may allow for a 'Sub-investigator' as a delegated duty to complete steps 1-3 of the assessment.

A. Assessment of Seriousness

This is based on the regulatory definitions of seriousness (patient / event outcome or action criteria). This, in most cases, is the responsibility of the PI, who will provide a definitive decision as to whether the AE results in any of the following:

- Results in death
- Is life threatening
- Results in patient hospitalisation or prolongs existing hospitalisation
- Results in persistent or significant disability/incapacity
- Results in a congenital anomaly / birth defect

To complete this assessment effectively, the following steps should be followed:

B. Assessment of Causality

A clinical assessment of whether the adverse event is likely to be related to the trial drug. All adverse events judged as having a reasonable suspected causal relationship (definitely, probably or possibly related) to the drug are adverse reactions. The local investigator responsible for the patient should make the immediate assessment, distinguishing suspected adverse reactions from unrelated adverse events.

C. Assessment of Expectedness

The evaluation of expectedness is based on knowledge of the adverse reaction and any relevant product information. The list of expected events should be based on:

- the Summary Product Characteristics (SPC) for the products under investigation for a licenced drug; and/or

- the investigator's brochure (IB) for a non-licenced drug.

To ensure accurate and concise reporting of all safety events, the following guide should be followed:

Figure.1- Reporting Steps for events that meet the definition of an AE/SAE as per protocol:

1) Record each untoward occurrence as separate AE/SAE, for example, nausea and vomiting should be recorded as separate events 1. Nausea and 2. Vomiting.

2) Document the nature of the adverse event(s) in an unambiguous way using precise and specific terminology

3) Record start and stop times and dates of the adverse event(s) as accurately as possible. Refer to the protocol for advice on estimate of dates

4) PI or delegated Research/ Clinical staff member (stated on the delegation log) to document the severity of the adverse event(s) as guided by the study protocol (usually mild, moderate or severe)

5) Document any action taken regarding the study drug or study procedures

6) Document any treatment/medication given, or action taken in relation to the AE/SAE. Document the outcome assessment, the PI will cover the following 3 areas: Seriousness, Causality and Expectedness

7) The Research team should ensure at this stage that their own records are updated making reference to the 'Portfolio Review Sheet' and the Project manager uploads onto Edge (SAE).

14.1 Adverse Event:

At each visit of the study, assessment of adverse events that might have occurred since the previous visit or that are occurring at that time should be elicited. Patients should also be encouraged from the outset of participation in any study to contact the research team at the time of any adverse event where possible. The Research staff will assess for adverse events at each study visit and report within the specified timeframe as stated in the Sponsor Protocol – or as soon as aware. In most cases this will be during a study visit when the patient is asked about or reports any adverse events that have occurred since the last study visit.

In general, an example of an AE can be any incident that happens to an individual that is different from previous; this maybe a fall or a headache, nausea or an abnormal laboratory finding. Moreover, it is dependant of what the trial specific protocol classifies as an AE.

AE Case Study:

This case study has been created for learning purposes, both the patient and study are fictional.

Jemima Puddleduck who is female, aged 81 has been identified as high-risk of bowel cancer. Jemima is currently enrolled on an interventional study called 'Pondlife'. This study gives medication to high-risk patients with the aim of preventing bowel cancer.
At the initial follow-up, Jemima reported to the research nurse that she had been experiencing dyspepsia.
The research nurse at the time checked the protocol for this study and looked at the definitions of AEs for this study. The research nurse also contacted the trial team for reassurance/guidance.
If it met AE criteria the research nurse would be reporting it, using the correct forms/databases and then make contact with the PI to complete the 3-step assessment. If it doesn't meet the criteria for an AE, then it is to be documented in the patients' medical notes.
In conclusion, Jemima's dyspepsia did not meet the criteria and was in fact a side-effect of the medicine she was taking for this study- this was noted in her medical notes.

14.1.1 Adverse Event Reporting:

The most important thing to remember is that if you think something should be reported, you should report it. When an adverse event occurs, the step-by-step guide in figure 1. of the Policy Content should be followed. In addition, some study protocols may require completion of study-specific adverse event reporting forms.

14.2 Serious Adverse Event:

Once a patient is recruited onto a trial/study SAEs should be assessed/discussed at each appointment with the patient. Participants should be asked if they have been admitted to hospital, had any accidents, used any new medications or changed concomitant medication regimens; all of which could be categorised as an SAE and should be confirmed through checking the study protocol.

All SAEs must be recorded as per protocol often from the time of consent. If there is any doubt as to whether a clinical observation is an SAE, the event should be recorded. Referring to the study protocol will help in this process as there are some conditions which do not require recording; for example, some dialysis patients who suffer from headache, nausea and itching, as well as infections and do not require hospitalisation, would not be recorded.
Each initial SAE will be assessed by the PI for Seriousness, Causality and Expectedness which may be reclassified as a Serious Adverse Event or Reaction based on prevailing circumstances.

SAE Case Study:

This case study has been created for learning purposes, both the patient and study are fictional.

Peter Rabbit who is male, aged 77 has been enrolled on a study called 'Veg Patch'. This is an interventional medicinal product (IMP) study, which is trialling different doses of medication for hypertension.
Peter Rabbit presented at Emergency Department over the weekend, with possible stroke symptoms. The Research admin team were made aware of this on the Monday morning via an automated email, which is generated via the SAE flag being present on PAS. This email was forwarded to the appropriate research study team. The Research nurse then checked the protocol for definitions of SAEs. The research nurse saw the patient on the stroke unit and contacted the local clinical trial team. The Research nurse asked them for guidance on initiating the SAE reporting as appropriate.
SAE- criteria met:
This was reported to the sponsor as an initial report, using the correct forms/ database. The Research Nurse informed the PI to complete the 3-step assessment.
In conclusion, the patient's condition/event did meet the criteria for an SAE screening. The SAE was recorded in the patients' medical records and further reported to the sponsor using the appropriate SAE form/entry on database. The SAE is also recorded on Edge (Research admin team to complete this).
The SAE is re-assessed by a Research Nurse, at appropriate time-points as outlined in the protocol e.g. on discharge home.
The SAE can now be assessed by the PI as being resolved completely or with sequalae/on-going on a follow up form, with or without an end date. This is to be reported in the patient medical records, CRF/eCRF/Database/Edge.

14.2.1 Serious Adverse Event Reporting:

The most important thing to remember is that all SAEs should be reported as per the protocol. Researchers must inform the study organising body as soon as becoming aware of the serious adverse event. Further details on informing the study organising body of Serious Adverse Events and emergency contact telephone numbers will be fully detailed in the study protocol.

An initial SAE report should contain only the patient's non-identifiable details, and the presumed diagnosis based on presenting symptoms. The SAE should ONLY be signed by the Principal or Sub-Investigator, and the seriousness, causality and expectedness assessment must only be undertaken by these members of staff. An un-signed SAE may be submitted to avoid delay in reporting the event. Where possible, the follow-up SAE should be sent within a further 24 hours, even if full diagnosis and management plan is not yet known. It is acceptable to send the first follow-up SAE with the comment 'no further information yet available' or 'results not back from laboratory/radiology'. A fully completed and PI-signed report must be sent

at the earliest opportunity. Requests from the study organising body for further information of the serious adverse event must be promptly responded to.

Reporting SAEs over a weekend – In accordance with GCP, the Researcher must notify the sponsor of an SAE as soon as they are aware of the event. If the Principal Investigator is on-call and in the hospital over the weekend, they must report it straight away. If the Research Nurse/ Research Project Manager is informed that a patient is admitted over the weekend (should they be working) they must report the SAE. Otherwise, the Research Nurse/ Research Project Manager would be alerted to the SAE event when they are next in work and would report the event immediately. This is the same for SAEs in the evening. On occasions where patients have been admitted late in the evening, if you are still in the hospital grounds and are aware of the admission, you must complete the initial report prior to leaving for the day.

When a Serious Adverse Event occurs, follow the steps in *Figure.1- Reporting Steps*. This figure outlines the steps taken for all safety reporting events.

14.3 SUSAR reporting:

Below is a description of Suspected Unexpected Serious Adverse Reactions (SUSAR). The reporting procedure for each is detailed as follows:

14.3.1 Suspected Unexpected Serious Adverse Reaction (SUSAR) Reporting:

A SUSAR (suspected unexpected serious adverse reaction) is a SAR which is ‘unexpected’, whereby the nature and severity are not consistent with the information about the medicinal product in question.

The trial protocol will include a list of known side effects for every drug in the study. Each serious adverse event should be checked in terms of expectedness. In cases where the event is not listed as expected or is a more serious event than expected, this should be considered as a SUSAR.

According to the ICH (International Conference for Harmonisation) guideline:

“The reporting of SUSARs to investigator(s)/institutions(s) and to the IRB(s)/IEC(s) should be undertaken in a manner that reflects the urgency of action required and should take into consideration the evolving knowledge of the safety profile of the product. Reporting of SUSARs to the investigators/institutions should be made in accordance with regulatory requirements. In some regions, periodic reporting of line listings with an overall safety assessment may be appropriate.”

If an SAE is deemed to be a SUSAR, a DATIX may be considered in exceptionally rare cases. If there is uncertainty whether a DATIX should be submitted; consult the Research Quality Governance Lead.

A SUSAR reported at another site may generate an Urgent Safety Measure, the process for which can be found in RESSOP004.

14.4 Breaches and Protocol Deviations:

This section details how to identify, process and report all breaches and protocol deviations.

14.4.1 Breaches and Reporting:

"A breach is defined as; likely to effect to a significant degree.

- The safety or physical or mental integrity of the subjects of the trial; or
- The scientific value of the trial"- MHRA

It is a mandatory requirement to report serious breaches of the clinical study protocol or GCP to the MHRA within 7 days of the awareness of the breach. Serious breaches are the responsibility of the sponsor, who will report the breach to MHRA GCP Inspectorate using the relevant documentation available on the MHRA website.

Breaches can be disagreed with but other delegated staff members within the trust. It would be expected that due diligence is exercised by the delegated staff to report the serious breach or contact the GCP Inspectorate to discuss this further, usually this would be performed and completed by the Research Quality Governance and Assistants. **It is key to remember- if you are unsure that something should be reported- report it anyway!**

An example of a breach can be found here:

https://mhrainspectorate.blog.gov.uk/2019/05/24/gcp-serious-breaches-the-2018-edition/

14.4.2 Protocol Deviations and Reporting:

Any unplanned excursion from the protocol that is not implemented or intended as a systematic change would be referred to as a 'protocol deviation'. It may also refer to any other unplanned, instance (s) of protocol non-compliance.

The ICH E3 Q&A R1 defines a protocol deviation as "…any change, divergence, or departure from the study design or procedures defined in the protocol.", and encourages sponsors not to use terms such as "violation" to describe a major protocol deviation to avoid confusion. Please note that violations are deviations that are deemed more "major" by the sponsor, and are not explicitly defined in ICH GCP.

To establish whether a protocol deviation has occurred the clarifying key principles are.

- An event occurred (e.g. not theoretical)
- The event is related to the protocol or document s referenced in the protocol (e.g. laboratory manual)
- The event is independent of fault, blame or circumstance- to ensure an objective approach to identification (e.g. sample tube broke en route to central laboratory).

As soon as the protocol deviation has been identified, it should be reported to the sponsor and recorded via patient medical notes, relevant CRF (eCRF), databases and

edge. In some cases, an approved deviation will be acknowledged by the sponsor as it may be 'known in advance', e.g. A patient is unable to attend their scheduled follow-up appointment within a specified window (protocol). The trial team will inform the sponsor who may provide approval of this deviation.

14.5 Follow-up of Adverse Events & Serious Adverse Events

Adverse events must be followed up according to the study protocol and adverse event report form until the symptoms cease, the condition is stable or unlikely to change. The adverse event will require an update by the PI or Assistant PI (with this delegated duty of reporting) on the outcome, to be recorded on the CRF/eCRF/Study Database and in the patient's medical notes as to the following:

1. Resolved
2. Resolved with sequalae
3. Persisting/ongoing
4. Worsening
5. Death
6. Not assessable

The investigator should keep an ongoing log of adverse events in the ISF that must be made available to the sponsor on request. Within Dorset County Hospital NHS Foundation Trust, a log of said events can be found on Edge database and on the Portfolio Review Sheet located on the Teams- Portfolio Updates channel.

14.5.1 Guidance on Pregnancy Follow-up:

Any pregnancy that occurs during trial IMP administration, whilst not an AE or SAE, requires monitoring and follow-up to term. Pregnancies and outcome will be included in signal detection and annual safety reports. The Chief Investigator will report any pregnancy occurring on a clinical trial via the SAE report form to the study organising body in the manner described within the study protocol. Each pregnancy will be followed up until the outcome of the pregnancy is known. The Chief Investigator will liaise with the relevant Obstetrician throughout the pregnancy. A database record of all pregnancies will be held by the study organising body, this will include follow-up to term and where appropriate, long-term follow-up of the baby may be required.

14.6 Blinding and Unblinding

Studies are often 'blinded' to prevent bias. Single blind is where the participant only, is blinded to which treatment they are receiving. Double-blinded is where the study team may not know either.
Where possible, the blind should be maintained however if unblinding is required, you should refer to the study protocol for guidance; this document can be found on the PDoc on DPR.
In the event of an emergency, where unblinding is necessary, follow the study specific guidance provided within the PDoc.

15 Legislation, References, local Policies and Guidelines

HRA legislation:
Common issues: Clinical - GOV.UK (www.gov.uk)
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/#researchteams

https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/

NIHR Guidance:
https://njl-admin.nihr.ac.uk/document/download/2035899

MHRA legislation:
https://www.legislation.gov.uk/uksi/2004/1031/contents

https://www.legislation.gov.uk/uksi/2004/1031/regulation/33

https://www.gov.uk/guidance/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues#suspected-unexpected-serious-adverse-reactions-susars

https://www.legislation.gov.uk/ukdsi/2019/9780111179116/contents
https://mhrainspectorate.blog.gov.uk/2019/05/24/gcp-serious-breaches-the-2018-edition/

References:
Microsoft Word - uksi_20041031_en.doc

ICH_E6(R3) 06-01-2025.pdf

Clinical trials for medicines: manage your authorisation, report safety issues - GOV.UK

https://www.ct-toolkit.ac.uk/routemap/safety-reporting

Appendix 1

EQUALITY IMPACT AND COMPLIANCE ASSESSMENT

1. General	
Title of Document	Research Safety Reporting
Purpose of Document	To explain the local process and requirements for reporting Adverse and Serious Adverse Events, as well as Suspected Unexpected Serious Adverse Reactions for both multicentre studies that DCH is taking part in and studies which are sponsored by DCH.
Intended Scope	Reference document for all staff of the research department and trust-wide staff participating in research.

2. Consultation	
Which groups/ associations/ bodies or individuals were consulted in the formulation of this document?	Circulated for review and comment to the Research Clinical Team, Research Project Management Team prior to review by the Research Quality Group/ R&D Management team within the research department
What was the impact of any feedback on the document?	Feedback was considered and incorporated into the final document as appropriate
Who was involved in the approval of the final document?	The research Quality Group and R&D Research department
Any other comments to record?	None

3. Equality Impact Assessment/Analysis		
Reference: who it may impact		
Age **Disability** **Ethnicity** **Gender reassignment** **Marriage/ Civil Partnership** **Pregnancy/ Maternity** **Religion and Belief** **Sex** **Sexual Orientation**	**Patients** **Members of the local community** **Voluntary Sector Groups**	**Staff Groups** **Volunteers**

ED&I Considerations: (Access, Communications, Service delivery, Cultural competence).	
Does the document positively or negatively affect certain staff or groups of staff? If so, please state how this is justified.	No
Does the document positively or negatively affect certain patients or groups of patients? Please state how this is justified.	No
What measures are proposed to address any inequity?	All adverse events reported as per protocol
Can the document be made available in alternative format or in translation?	Yes as per protocol (electronic or paper)

4. Compliance Assessment	
Does the document comply with relevant employment/ equality legislation or Trust standards? Please specify.	Yes

5. Document assessed by:	
Name	Anthony Homer
Post Title/ Position	Research governance and Quality lead
Date	19th February 2026

Appendix 2

Data Protection Impact Assessment (DPIA) Screening Questions

These screening questions should be used to inform whether a full DPIA is necessary - if you are uncertain, please talk to information.governance@dchft.nhs.uk. See the last page for information about why we must do this.

Please complete all sections

Title of Project	Research			
Brief description	Standardisation of the Research safety reporting process to achieve quality and safety standards at Dorset County Hospital when completing safety reports for participants			
Completed by:				
Name	Anthony Homer			
Title	Research Governance and Quality Lead			
Department	Research			
Email	Anthony.homer@dchft.dchft.nhs.uk			
Date	19th February 2026			
		Yes	**No**	**Unknown**
1.	Will the project involve the collection of new, person identifiable information[1], or potentially identifiable information, about individuals (patients and/or staff)?		**No**	
2.	Will the project compel individuals to provide information about themselves, or involve the processing of personal data not obtained directly from the individual? *i.e., where they will have little awareness or choice, or it is impossible, or would involve disproportionate effort to inform the individuals that the processing is taking place.*		**No**	
3.	Will identifiable information about individuals be shared with other organisations or people who have not previously had routine access to the information?		**No**	
4.	Are you using information about individuals for a purpose it is not currently used for? *i.e., using data collected to provide care for an evaluation of service development, or data matching from multiple sources.*		**No**	
5.	Where information about individuals is being used, would this be likely to raise privacy concerns or expectations? *i.e., will it include health records, criminal records, or other information that people may consider to be sensitive** and private, and may cause them concern or distress.*		**No**	
6.	Will the project require you to contact individuals in ways which they may find intrusive?		**No**	

1

	i.e., telephoning or emailing them without their prior consent.			
7.	Will the project result in you making decisions in ways which could have a significant impact on individuals? *i.e., will it affect the care a person receives?*		**No**	
8.	Does the project involve you using new technology which might be perceived as being privacy intrusive? *i.e., using biometrics, facial recognition, artificial intelligence, or automated decision making.*		**No**	
9.	Is a service being transferred to a new supplier (re-contracted) and the end of an existing contract, or is the processing of identifiable/potentially identifiable data being moved to a new organisation?		**No**	
10.	Will the project involve systematic monitoring of a publicly accessible area on a large scale? *i.e., use of CCTV.*		**No**	
11.	Will the project involve the targeting of children or other vulnerable individuals? *i.e., for marketing purposes, profiling or other automated decision making*		**No**	
12.	Will designated staff need approved access to this information, either by team membership or individual log-in? *i.e., shared file access, separate software username and password, information asset*		**No**	
13.	What is the lawful basis for using this data? *√ all that apply*			
	A. Article 6(1)(e) - Public Task (direct healthcare)			
	B. Article 9(2)(h) (the processing is necessary for health or social care purposes)			
	C. Consent			**Yes**
	D. Unknown			

- If all answers are **NO** then please file this with your project files to document that you have considered any possible risk to data.
- If any are **YES** or **UNKNOWN** please forward this document for review and next steps to informationgovernance@dchft.nhs.uk

OUTCOME

☒ No Risk to data, or No data – file locally

☐ Risk to data – forward to informationgovernance@dchft.nhs.uk

- ☐ Low Risk - approved by IG – file locally
- ☐ High Risk – complete full DPIA template and submit to IG

Name of Information Asset Owner Anthony Homer

Name of Information Asset Administrator

Signed by Project Lead Anthony Homer Date: 19th February 2026

Signed by Information Governance (N/A) Date:
(if appropriate)