Gloucestershire Hospitals
NHS Foundation Trust

SOP 20: Adverse Event and Reaction Safety Reporting

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust and University Hospitals Bristol NHS Foundation Trust who gave permission to use their templates in the development of these SOPs.

Version History Log

This area will be updated with details of all changes made to the SOP whether due for full review or not.

Version	Details of Change	Date Implemented
1.0	Original	SOP 02
2.0	Reviewed and updated along with reorganisation into the Gloucestershire R&D Consortium suite of SOPs	10/02/2015
2.1	Review and addition of related SOPs	10/03/2017
3.0	Rebranding to GHNHSFT, updating of contact details and reference documents. Inclusion of section 5.2.2 SAEs for CTIMPS hosted by the Trust	31/03/2018
4.0	Updating of webpage links Correction of typographical errors Formatting, simplified contents page, Updated legislation, medical device information, Additional details regarding responsibilities Removal of details regarding the use of a fax machine Removal of SOP categories and change of reference codes Changed R&D to R&I	03/01/2024

This SOP will be reviewed every two years unless changes to any relevant legislation require otherwise

Related Documents:

SOPs
SOP 02 - Research documentation and file management
SOP 12 - Trial management system - using EDGE
SOP 19 - Periodic Safety Reporting
SOP 23 - Urgent Safety Measures

Glossary

AE	Adverse Event
AR	Adverse Reaction
CI	Chief Investigator
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
ICH GCP	International Conference for Harmonisation of Good Clinical Practice
IMP	Investigational Medicinal Product
MHRA	Medicines and Healthcare products Regulatory Agency
NIMP	Non-Investigational Medicinal Product
PI	Principal Investigator
R&I	Research & Innovation
REC	Research Ethics Committee
RSI	Reference Safety Information
SAE	Serious Adverse Event
SAR	Serious Adverse Reaction
SmPC	Summary of Product Characteristics
SUSAR	Suspected Unexpected Serious Adverse Reactions

Contents

1. Purpose, Introduction, and Background

This SOP describes the process for recording, managing and reporting adverse events for Gloucestershire Hospitals NHS Foundation Trust (GHNHSFT) sponsored studies of both Investigational Medicinal Products (IMPs) and non-IMPs, but the principles are relevant for all clinical studies.

In accordance with the UK policy Framework for Health & Social Care Research, GHNHSFT must have systems in place to record, investigate and report adverse incidents arising from studies undertaken in the Trust.

Furthermore, the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Medicines for Human Use (Clinical Trials) (Amendment EU exit) Regulations 2019 which apply to all clinical trials involving Investigational Medicinal Products (CTIMPs), and the Medical Devices Regulations 2002 specify the reporting requirements for research related adverse events. To breach these requirements constitutes a breach in criminal law.

As well as research related adverse events, adverse incidents occur on research studies. Adverse incidents, whether clinical, non-clinical or near misses can involve research patients and research staff in the same way as patients, staff and visitors involved in routine care. It is important that adverse incidents that occur in the context of research are reported in the same way as non-research related adverse incidents (see Section 4.10 and 5.4).

2. Who Should Use This SOP

This SOP should be used by investigators and research staff involved in studies sponsored or co-sponsored by the Trust, or where the R&I Department has contracted to provide pharmacovigilance services for a particular study.

For externally sponsored studies hosted by the Trust, Adverse Event reporting will follow the International Conference for Harmonisation of Good Clinical Practice (ICH GCP) guidelines and the Sponsor's requirements with R&I department notification.

3. When this SOP is to be used

Recording and reporting of Adverse Events (AEs), including Adverse Reactions (ARs), Serious Adverse Events (SAEs), Serious Adverse Reactions (SARs), and Suspected Unexpected Serious Adverse Reactions (SUSARs) should be managed in line with the reporting procedure of the sponsor of the research study.

Where the Trust is the sponsor or co-sponsor, this SOP and the study protocol must be followed.

4. Definitions

4.1 Adverse Event (AE)

An untoward medical occurrence in a participant to whom a medicinal product/medical device/intervention has been administered, including occurrences which are not necessarily caused by or related to that product.

An adverse event can therefore be any unfavourable and unintended sign (including abnormal lab results), symptom or disease temporally associated with the use of the medicinal product/medical device/intervention, whether or not considered to be related to the medicinal product/medical device/ intervention.

The definition of adverse event given above is that used in the clinical trials regulations however, for the avoidance of doubt, when following this SOP **all** AE/SAEs should be collected for all study subjects from the commencement of any study related procedures (including screening procedures). This is the default

position for all Trust sponsored studies and any deviation from this must be agreed by the Sponsor prior to the start of the study and documented accordingly.

4.2 Adverse Reaction (AR)

Any untoward and unintended response in a subject to an investigational medicinal product/medical device/intervention which is related to any dose administered to that subject.

Any adverse event judged by either the reporting investigator or the sponsor as having reasonable causal relationship to an IMP/medical device/intervention qualifies as an AR; there is evidence or argument to suggest a causal relationship.

All adverse reactions are adverse events.

4.3 Unexpected Adverse Reaction (UAR)

An adverse reaction, the nature and severity of which is not consistent with the information set out in the Reference Safety Information, which may be–

- the Summary of Product Characteristics (SmPC)(for a product with a marketing authorisation),
- the investigator's brochure(for any other IMP).
- or other document containing equivalent information e.g., the study protocol

When the outcome of the adverse reaction is not consistent with the reference safety information this adverse reaction should be considered as unexpected. All unexpected adverse reactions are adverse events.

4.4 Serious Adverse Event (SAE)

An adverse event, adverse reaction, or unexpected adverse reaction is defined as serious if it:

- results in death,
- is life-threatening,

- requires hospitalisation or prolongation of existing hospitalisation,
- results in persistent or significant disability or incapacity, or
- consists of a congenital anomaly or birth defect.

Life threatening in the definition of an SAE/SAR refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event that hypothetically might have caused death if it were more severe. Medical judgement should be exercised in deciding whether an SAE/SAR is serious. SAE/SARs that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one or the other outcomes listed in the definition above, should also be considered serious.

4.5 Suspected Serious Adverse Reaction (SSAR)

Any serious adverse reaction that is suspected (possibly, probably or definitely) to be related to the investigational medicinal product/medical device/intervention.

4.6 Suspected Unexpected Serious Adverse Reaction (SUSAR)

A SUSAR 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 in the agreed Reference Safety Information, examples of which are:

- in the case of a product with a marketing authorisation, in the summary of product characteristics for that product;
- in the case of any other investigational medicinal product, in the investigator’s brochure relating to the study in question.

4.7 Reference Safety Information

A list of medical events that defines which reactions are expected for the IMP being administered to clinical study subjects, and so do not require expedited reporting to the Competent Authority. Examples are the Investigator Brochure and Summary of product characteristics.

4.8 Investigational Medicinal Product (IMP)

A pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical study including a medicinal product which has a marketing authorisation but is, for the purposes of the study, being used or assembled (formulated or packaged) in a way different from the approved form or being used for an unapproved indication or when used to gain further information about an approved use.

4.9 Non-Investigational Medicinal Product (NIMP)

Products that are not the object of investigation (i.e., other than the tested product, placebo or active comparator) may be supplied to subjects participating in the study and used in accordance with the protocol. This might be for preventative, diagnostic or therapeutic reasons and/or to ensure that adequate medical care is provided for the subject. These medicinal products do not fall within the definition of Investigational Medicinal Products (IMPs) in Directive 2001/20/EC.

4.10 Adverse Incident

Any incident/accident, near miss or untoward event which had or may have had, the potential to cause harm, dissatisfaction or injury to persons, loss or damage to property. This definition includes hazards, accident, ill health, dangerous occurrences and near misses. It is important that adverse incidents occurring in the context of research are treated in the same way as non-research related adverse incidents and reported in accordance with GHNHSFT policy B0393 Managing, Reporting and reviewing of Incidents/Accidents, including Serious Incidents.

An adverse incident may also be an adverse event and should be reported through both routes.

4.11 Urgent Safety Measures

The sponsor and investigator may take appropriate action to protect a research participant from an immediate hazard to their health and safety. This measure can be taken before seeking an approval from the competent authorities.

4.12 Responsibilities

The Sponsor, Chief Investigator/Principal Investigator (CI/PI) must ensure that the dignity, rights, safety and wellbeing of subjects are given priority at all times and must take appropriate action to ensure the safety of all staff and participants in the study.

For GHNHSFT sponsored studies, the responsibility of safety reporting is delegated to the CI and PIs. In a multi-site study, the CI has co-ordinating responsibility for reporting adverse events to the Medicines and Healthcare products Regulatory Agency (MHRA) and the relevant Research Ethics Committee (REC). The PI has responsibility for the research at a local site. The PI is responsible for informing the CI of all adverse events that occur at their site. There should be one PI per site. In the case of a single-site study, the CI and PI should be the same individual.

5. Chief Investigator/ Principal Investigator Responsibilities in the event of Adverse Events

5.1 All Adverse Events

In the event of an adverse event/reaction, the CI/PI/Co-Investigator (Co-I) (or delegated member of research team) must review all documentation (e.g., hospital

notes, laboratory and diagnostic reports) relevant to the event. The investigator will make an assessment of intensity, causality, expectedness and seriousness. Detailed guidance on making this assessment is given in section 6.

Except where the protocol states otherwise, all adverse events/reactions should be recorded in detail to allow analysis at a later stage. A template for recording adverse events is provided (Appendix 1 and Appendix 2 for research team use and Appendix 3 for R&I department use for Trust Sponsored studies). Adverse events/reactions will also be recorded (Appendix 6) in the patient's medical notes or source data where this is not the medical notes. This will include the assessment of intensity, causality, severity and seriousness.

Adverse events and/or laboratory abnormalities identified in the protocol as critical to the evaluations of the safety of the study shall be reported to the sponsor in accordance with the reporting requirements documented in the protocol.

If the protocol needs to be amended as a result of actions that the investigator has taken to maintain the safety of staff and patients, the investigator must ensure appropriate regulatory permissions are obtained for the amendment.
If the amendment is due to implementation of urgent safety measures, the amendment will be implemented immediately and then submitted for necessary approvals. Please reference SOP 23 Urgent Safety Measures.

The Investigator should keep an ongoing log of adverse events in the Investigator Site File (ISF) that must be made available to the Sponsor on request (see Appendix 4) and on the local trial management system EDGE for GHNHSFT Sponsored trials.

The CI will review all adverse events/reactions reported to identify any trends which may require action.

The CI will keep the Sponsor, the main REC and the MHRA informed of any significant findings and recommendations by an independent Data Monitoring Committee or equivalent body where one has been established for the study.
At the conclusion of the sponsored studies all adverse event/reactions, recorded during a study must be subject to statistical analysis and that analysis and any subsequent conclusions included in the final study report.

5.2 Serious Adverse Events (SAEs)/SUSAR

5.2.1 Studies Sponsored by the Trust

Immediately after becoming aware of a serious adverse event (and within 24 hours) the investigator or an appropriate member of the research team must notify the Sponsor, GHNHSFT R&I Department in writing. Written reports should be made by completing a Research Related SAE/SUSAR Initial Report Form (Appendix 1). The initial report will include as much information as is available at the time and should be signed by a suitable qualified medical doctor, usually the PI or delegated investigator, to confirm their review and assessment of the SAE. This form must be emailed to the R&I Department, using the generic email account ghn-tr.glos.rdsu@nhs.net . For the avoidance of doubt, the date that the initial notification is issued to the R&I Department is day 0 of the reporting timescales. The R&I Department will acknowledge receipt of the SAE notification by 3pm the following working day; taking into account emails sent out of office hours. If acknowledgement of the SAE is not received by the Investigator by this time, then it is the responsibility of the Investigator to contact the R&I Department immediately. On receipt of a notification of an SAE/SUSAR the Sponsor, GHNHSFT R&I Department will follow the HRA guidelines; link to these guidelines will be found in the reference section of this SOP.

In addition, the following bodies must also be notified in a timely fashion where applicable. It is strongly recommended that this be at the same time as notifying the sponsor:

- The Chief Investigator

- Any other persons or bodies specified in the protocol or clinical trial agreement (e.g., Data Monitoring Committee or Trial Management committee)

The only exception is where the protocol or other relevant Reference Safety Information (RSI), for example Investigator Brochure or protocol identifies the event as not requiring immediate reporting. Laboratory parameters may also require reporting within the same timescales as SAEs and these should be specified in the protocol.

The Investigator (or delegated person) will submit any additional information missing from the initial report signed, within 72 hours of the initial report to the R&I Department and the bodies specified above (where applicable).

After the initial report the investigator is required to actively follow up the subject until either

(i) the SAE resolves, or

(ii) (ii) the Sponsor and CI/PI agree that no further follow-up is required.

This decision must be documented in the Trial Master File, on EDGE and in the R&I folder.

Investigators (or delegated persons) will provide follow-up information, each time new information is available, using a Research Related SAE/SUSAR Follow-up Report Form (Appendix 2)

For all studies the Chief Investigator will inform all Principal Investigators of relevant information about SAEs that could adversely affect the safety of subjects.

Although there is no requirement for expedited reporting of SAEs that are not deemed to be related to the intervention and unexpected, they must be documented in Development Safety Update Reports and Annual Progress Reports as detailed in the SOP 19 - Safety Reporting.

The Investigator must maintain an up-to-date log of all SAEs using the ISF SAE log (Appendix 5) and EDGE SAE workflow. This log will be reconciled with the R&I Department's log during trial monitoring. The frequency of this reconciliation may be defined in the trial monitoring plan. As a minimum, reconciliation will take place as part of the database check prior to database lock.

For SAEs that are deemed 'possibly, probably or definitely related' and 'unexpected' refer to section 5.3 below.

5.2.2 For studies hosted by the Trust

The reporting requirements of the research protocol will be followed for reporting SAEs/SUSARs. The SAE/SUSAR will be logged on EDGE (Clinical Trials Management system) on the conclusion of the SAE/SUSAR or the end of the reporting requirements as defined in the study protocol. These will be reviewed at the R&I Senior Management Team Governance meeting.

5.3 Suspected Unexpected Serious Adverse Reactions (SUSAR)

Where the SAE has been deemed by the Investigator or Sponsor (taking advice from an independent medical expert where necessary) to be 'possibly, probably or definitely related' and 'unexpected' additional expedited reporting requirements exist.

For all multi-site studies, the CI must inform all PI of SUSARs occurring on the study in a timely manner. It is the responsibility of the CI to communicate all information to the PIs, in particular any information that could adversely affect the safety of subjects. This notification must be documented.

GHNHSFT R&I Department will (on behalf of the Sponsor) notify the MHRA and Main REC of SUSARs within the specified reporting timescales. However, the R&I Department reserves the right to delegate this responsibility to the CI and this decision will be documented.

5.4 Adverse Incidents (AI)

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 must therefore be reported in accordance with the Trust's own Adverse Incident Reporting Procedure/System DATIX. An example of a research related adverse incident may be lost drugs. This is not an AE but should be reported as an AI.

Events that are both Adverse Incidents and Adverse Events MUST be reported independently following both processes and procedures previously outlined.

All Adverse Incidents that are reported as occurring on research studies taking place in the Trust are reviewed by the R&I Department and are reviewed at the SMT research governance meeting

6. Assessment of Adverse Events

6.1 Intensity

The assessment of intensity will be based on the Investigator's clinical judgement using the following definitions:

- Mild: An event that is easily tolerated by the patient, causing minimal discomfort and not interfering with everyday activities.
- Moderate: An event that is sufficiently discomforting to interfere with normal everyday activities.
- Severe: An event that prevents normal everyday activities.

The term severity is often used to describe the intensity (severity) of a specific event. This is not the same as 'seriousness', which is based on patient/event outcome or action criteria.

6.2 Causality

Prior to the study commencing the CI will determine what will be used as the RSI to determine causality of any adverse events. An RSI is required for the active IMP and for any comparator IMPs.

The CI, Sponsor and all the PIs will be provided with the approved RSI prior to the study commencing. If the CI and/or sponsor is informed of any updates to the document being used as the RSI, the sponsor and CI must agree whether this should replace the existing RSI. If it is agreed, an amendment will be submitted to the MHRA and only once approved will the updated RSI be used, except in the case of Urgent Safety Measures.

The RSI used to assess causality and expectedness must be one which was MHRA approved at the time of the onset of the event.

The relationship between the drug/device/procedure and the occurrence of each adverse event will be assessed and categorised as below. The investigator will use the agreed RSI in conjunction with their clinical judgement to determine the relationship. Alternative causes, such as natural history of the underlying diseases, concomitant therapy, other risk factors etc. will be considered.

- Not related: Temporal relationship of the onset of the event, relative to administration of the product, is not reasonable or another cause can by itself explain the occurrence of the event.
- Unlikely: Temporal relationship of the onset of the event, relative to administration of the product, is likely to have another cause which can by itself explain the occurrence of the event.

- *Possibly related: Temporal relationship of the onset of the event, relative to administration of the product, is reasonable but the event could have been due to another, equally likely cause.
- *Probably related: Temporal relationship of the onset of the event, relative to administration of the product, is reasonable and the event is more likely explained by the product than any other cause.
- *Definitely related: Temporal relationship of the onset of the event, relative to administration of the product, is reasonable and there is no other cause to explain the event, or a re-challenge (if feasible) is positive.

*Where an event is assessed as possibly related, probably related, definitely related, the event is **an adverse reaction (AR).**

6.3 Expectedness

The expectedness of an adverse reaction shall be determined according to the RSI and as defined in the study protocol

- Expected: Reaction previously identified and described in the RSI and/or protocol
- Unexpected: Reaction not previously described in the RSI and/or protocol
  - Adverse reactions must be considered as unexpected if they add significant information on the specificity or severity of an expected adverse reaction.
  - The protocol must identify the RSI used.

6.4 Seriousness

An event is considered serious if it meets one or more of the following criteria:

- Results in death
- Is life-threatening
- Requires hospitalisation or prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Consists of a congenital anomaly or birth defect

7. References

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

Appendix 1

RESEARCH RELATED SAE/SUSAR INITIAL REPORT FORM (Page 1 of 3)

R&I use only: case reference number		Date report received by R&I	

1. Person making report	
Name:	

Job title/role in study:	
Contact address:	
Email address:	
Contact Telephone No:	

2. Details of study	
Title:	R&I Ref:
	Ethics No:
	EudraCT No (CTIMP studies only):

3. Details of subject affected by SAE/SUSAR (enter details available without unblinding subject)						
Participant study ID	Hospital Number	Initials	DOB	Gender	Weight	Height

4. Details of SAE/SUSAR			
Full description of event/reaction, including body site, reported signs and symptoms and diagnosis where possible:			
Event is defined as serious because it (tick as many as apply): ☐ resulted in death ☐ is/was life-threatening ☐ required hospitalisation ☐ prolonged an ongoing hospitalisation ☐ resulted in persistent or significant disability/incapacity ☐ resulted in a congenital anomaly or birth defect ☐ other – please specify*		*Specify:	
Maximum intensity (up until time of report)		Mild ☐	Moderate ☐ Severe ☐
Onset Date	**Onset Time (if known)**	**End date**	**End time (if known)**
Date Investigator aware of SAE	**Date SAE Initial report emailed**		**Time SAE Initial report emailed**

Signature of person completing page:		Date:	
Print name:		Job title:	

RESEARCH RELATED SAE/SUSAR INITIAL REPORT FORM (Page 2 of 3)

5. Outcome		
☐ **Resolved***	☐ **Ongoing***	☐ **Died* (give cause and PM details if available)**
***Give details:**		
Was the patient withdrawn from the study?	**Yes** ☐	**No** ☐

6. Location of (onset of) SAE
Setting (e.g. hospital*, home, GP, nursing home):
Exact location:

7. Action taken and further information
Please describe action taken:
Other information relevant to assessment of case e.g. medical history, family history, test results.

Signature of person completing page:		**Date:**	
Print name:		**Job title:**	

RESEARCH RELATED SAE/SUSAR <u>INITIAL</u> REPORT FORM (Page 3 of 3)

8. Causality and Expectedness (to be completed by physician)		
Is the SAE related to the drug/device/intervention? ☐ **Not related** ☐ **Unlikely to be related** ☐ **Possibly related*** ☐ **Probably related*** ☐ **Definitely related***	***If possibly, probably or definitely related, was the SAE unexpected?** ☐ **Yes[1]** ☐ **No[2]** **(Unexpected means not described in the protocol or reference document such as IB or SmPC)**	**1 - The SAE is a SUSAR. Please complete and return all sections of the follow up report form when further information is available and complete R&D/F47 immediately.** **2 - The SAE is not a SUSAR. Please complete and return the follow up report form when further information is available.**

9. Additional information (refer to section number)	
Section no.	**Further information**

Signature of person completing page:		**Date:**	
Print name:		**Job title:**	

10. Chief/Principal Investigator, or delegated physician (at this site)	
Name:	
Job title/role in study:	
Contact address:	
Email address:	
Telephone No:	
Signature:	
I confirm that the contents of this form are accurate and complete	

Appendix 2

RESEARCH RELATED SAE/SUSAR FOLLOW UP REPORT FORM

R&I Use only:

Trial:		SAE reference number	Issued by R&I for initial SAE report
Report number:	e.g. Followup 1	Date Received	dd-mm-yyy

To be completed by the person filling in the SAE form					
Date of initial report		*Participant study ID*		*Participant initials*	

1. Further details of SAE/SUSAR			
Further details of event/reaction, including body site, reported signs and symptoms and diagnosis where possible:			
Maximum intensity (up until time of follow up report)	Mild ☐	Moderate ☐	Severe ☐

2. Outcome		
☐ Resolved*	☐ Ongoing*	☐ Died* (give cause and PM details if available)
*Give details (include end date and time where applicable):		
Was the patient withdrawn from the study?	Yes ☐	No ☐

3. Additional action taken and further information since initial report
Please describe further action taken:
Has the investigator assessment in the initial report form changed (provide reason):

Further information or missing data relevant to assessment of case e.g. medical history, family history, test results.

Signature of Chief /Principal Investigator or delegated physician: Name (print please): Date: I confirm that the contents of this form are accurate and complete

Appendix 3

RESEARCH RELATED SAE/SUSAR SPONSOR REPORT FORM

R&I Reference Number:	
Short Study Title:	
EudraCT Number:	
SAE reference number issued by R&I:	

1. Sponsor assessment of causality		
List the reports considered when making the Sponsor assessment		☐ Initial report ☐ Follow up report #1 ☐ Follow up report #2 ☐ Other ……..
Is the SAE related to the drug/device/intervention? ☐ Not related ☐ Unlikely to be related ☐ Possibly related* ☐ Probably related* ☐ Definitely related*	***If possibly, probably or definitely related, was the SAE unexpected? ☐ Yes[1] ☐ No[2] (Unexpected means not described in the protocol or other product information i.e. IB or SmPC)	1 - The SAE is a SUSAR. Proceed with unblinded assessment and complete sections 2 and 3. 2 - The SAE is not a SUSAR. Complete section 3.

3. Administrative and sponsor details	
Name of person performing sponsor assessment:	Contact Number:
Signature of person performing sponsor assessment:	Date:
Name of Sponsor Representative	Contact Number:
Signature of Sponsor representative:	Date:

Appendix 4

AE Log

Study Title:			**Chief/Principal Investigator:**		
R&I Reference Number:			**EUDRACT Number:**		
AE Reference number	Participant ID	Date of Event dd-mm-yyyy	Brief Description of Event	SUSAR (Y/N)	Initials of individual making entry

Appendix 5

SAE Log

Study Title:			**Chief/Principal Investigator:**		
R&I Reference Number:			**EUDRACT Number:**		
SAE Reference number	Participant ID	Date of Event dd-mm-yyyy	Brief Description of Event	SUSAR (Y/N)	Initials of individual making entry

Appendix 6

RESEARCH RELATED ADVERSE EVENT RECORDING TEMPLATE

STUDY TITLE:	
EudraCT No:	
Ethics Reference:	
R&I Reference:	

PATIENT/VOLUNTEER ID:

AE NUMBER FOR THIS PARTICIPANT:

Description of Event	Start date:	End date: (where no end date exists as patient concludes involvement in the study with ongoing AE then insert NR here)

Assessment			
Intensity:	☐ mild ☐ moderate ☐ severe	Expectedness	☐ expected ☐ unexpected i.e. not described in protocol, SmPC or IB
Causality: Relationship to study drug/ intervent-ion	☐ not related ☐ unlikely to be related ☐ possibly related ☐ probably related ☐ definitely related	Seriousness	☐ Not serious ☐ Results in death* ☐ Life threatening* ☐ Results in hospitalisation or prolongation of existing hospitalisation* ☐ Results in disability or incapacity* ☐ Congenital anomaly or birth defect* ☐ Other (please specify)*

* Event is considered serious – report to the Sponsor and/or R&I Unit within 24 hours using the SAE/ SUSAR reporting forms provided by the Sponsor . Where none is provided use the Research Related SAE/SUSAR Initial Report Form