Safety Reporting in Research Trials (Clinical and Healthy Volunteers)

It is a requirement for researchers to produce a protocol to describe their procedures for monitoring for any adverse events that occur to participants/patients in research trials. This should specify when monitoring will occur, who is responsible for it and how any such events will be recorded and reported. The Principal Investigator (PI) must ensure that all researchers on the team are aware of this information. For doctoral students, the supervisor needs to discuss completion of the protocol with the student, approve the final version before it is submitted to research ethics and keep a copy. Supervisors should be named as an additional source to whom participants can report adverse events if the student is unavailable.

Definitions of Adverse Events:

The NHS definitions are adopted for both NHS and University based research.

1. In clinical trials of medicinal products or dietary supplements

Suspected Serious Adverse Reaction (SSAR)

A *suspected serious adverse reaction* is an untoward and unintended response to a research intervention that:
(a) results in death;
(b) is life-threatening;
(c) requires hospitalisation or prolongation of existing hospitalisation;
(d) results in persistent or significant disability or incapacity; or
(e) consists of a congenital anomaly or birth defect.

Suspected Unexpected Serious Adverse Reaction (SUSAR)

An adverse reaction is *unexpected* if its nature and severity are not consistent with the information about the medicinal product/ intervention in question set out:

- In the case of a product with marketing authorisation, in the Summary of Product Characteristics for that product.
- In the case of any other investigations of medicinal products, in the Investigator's Brochure relating to the trial in question. (The Investigator's Brochure contains full details relating to the development of a drug and dosage recommendations etc. Full details can be found at http://www.chcuk.co.uk/pdf/2011-03-12_GCP_Considerations_Investigators_Brochure_(CHCUK).pdf

2. Serious Adverse Event

In the NHS this label applies to all research that does not involve clinical trials of medicinal products. This distinction will be applied in the University context.

A *serious adverse event* (SAE) is defined as an untoward occurrence that:
(a) results in death;
(b) is life-threatening;
(c) requires hospitalisation or prolongation of existing hospitalisation;
(d) results in persistent or significant disability or incapacity;
(e) consists of a congenital anomaly or birth defect; or
(f) is otherwise considered medically significant by the investigator.

NB An SAE occurring to a research participant should be reported to the Research Ethics Committee (University or NHS) that approved the study when in the opinion of the PI the event was:

- *Related* – that is, it resulted from administration of any of the research procedures, and
- *Unexpected* – that is, the type of event is not listed in the protocol as an expected occurrence.

(Procedure for doing this is detailed later)

3. Adverse Events
These are less serious and records should still be kept by the research team in case of escalation.

1. RESEARCH BASED IN THE NHS WHERE THE HOSPITAL TRUST IS SPONSOR

The Standard Operating Procedures for the hospital area concerned (e.g. Sheffield Teaching Hospitals) will be adopted, which includes notifying the NHS Ethics Committee, with the addition of the key points identified below.

Key additions:

1.0. In line with the University's Principles of Integrity in Research and Procedures for Dealing with Allegations of Research Misconduct (10th Edition 2020); a SAE must be reported to the Head of Research Ethics (Dr Mayur Ranchordas) within 24 hours of discovery by the PI.

1.1. An email must be sent to EthicsSupport@shu.ac.uk ensuring SAE appears in the subject title. The email should include:

- The SHU Converis ethics reference number
- Funder reference (for externally funded projects)

1.2. Reporting should take place in parallel with that described for the hospital area as it is critical that the hospital process is followed but that the University, as sponsor, is informed and can take action as necessary in consultation with the Hospital's Research Department.

1.3. SAE report forms provided by the hospital trust will be used to minimise any duplication of effort and consistency of reporting. The University will enter all SAE reports onto the ethics module of our Research Management System (Converis) - linked to the original research proposal

1.4. Communications and reporting from the Research Department at the Hospital relating to a SAE should include the University at EthicsSupport@shu.ac.uk.

1.5. Decisions made by the Director of R&D at the Trust (or equivalent) have the ultimate authority in consultation with the University as Sponsor.

1.6. The University Registry will be notified by the Head of Research Ethics in case of possible future legal action.

2. ALL RESEARCH SPONSORED BY SHEFFIELD HALLAM UNIVERSITY CONDUCTED IN THE NHS OR THE UNIVERSITY

Researchers undertaking research trials of medicinal products or medicinal type products such as dietary supplements or other foods/ liquids, or medical devices, or behavioural interventions are required to:
a) risk assess for the likelihood of SAEs,
b) specify how they will monitor for SAEs in the course of the study
c) comply with the University reporting requirements should an SAE arise.
This information should be in the Risk Assessment Form that the PI needs to produce before the study is approved.

Reporting Requirements

2.1. The University Adverse Events Recording Proforma should be used for noting any adverse events reported by research participants.

2.2. In line with the University's Principles of Integrity in Research and Procedures for Dealing with Allegations of Research Misconduct (10th Edition 2020); a SAE must be reported to the Head of Research Ethics (Dr Mayur Ranchordas) within 24 hours of discovery by the Principal Investigator.

2.3. An email must be sent to EthicsSupport@shu.ac.uk ensuring SAE appears in the subject title. The email should include:

- The SHU Converis ethics reference number
- Funder reference (for externally funded projects)

2.4. The Head of Research Ethics will communicate with the PI and/or supervisor for PhD studies if clarification is required.

2.5. The Head of Research Ethics will notify the PVC Research and Innovation.

2.6. The PVC Research and Innovation will have ultimate authority to make decisions advised by the Head of Research Ethics.

2.7. The University Registry will be notified by the Head of Research Ethics in case of possible future legal action.

2.8. The PI must complete a Serious Adverse Event Report within **10 working days** of becoming aware of the event. It must be signed and dated and sent to EthicsSupport@shu.ac.uk for the attention of the Head of Research Ethics (Dr Mayur Ranchordas). The PI should retain a signed copy.

2.8. Research and Innovation Services will archive all associated documentation in the Converis ethics file for the research project.

ADVERSE EVENTS RECORDING PROFORMA FOR UNIVERSITY STUDIES **Sheet number ____ of ____**

Full title of study:	
SHU Reference Number	
Funder Reference	
Research sponsor:	

Participant/ patient ID	**Description of Event**	**Start date**	**Duration/End date**	**Outcome**	*** Sequelae (i.e. symptoms/condition)**
				☐ Resolved ☐ Ongoing ☐ Ongoing with sequelae*	
Assessment					
Intensity	☐ mild ☐ moderate ☐ severe	**Expectedness**	☐ expected ☐ unexpected i.e. not described in protocol, product information or Investigator Brochure.		
Causality	☐ 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 Research and Innovation Services within 24 hours to EthicsSupport@shu.ac.uk with SAE in the subject title. The email should include 1) the SHU reference number for the study and 2) the funder reference.**

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REPORT OF SERIOUS ADVERSE EVENT (SAE)

*The Principal Investigator should report any SAE that is both related to the research procedures and is unexpected. This report must be completed within **10 working days** of the PI becoming aware of the event and must be signed and dated and sent to EthicsSupport@shu.ac.uk for the attention of the Head of Research Ethics (Dr Mayur Ranchordas). The PI should retain a signed copy.*

Date of adverse event:			
Reported by:		***Date:***	
Reported to:		***Date***	

1. Details of Principal Investigator

Name:	
Research Centre/Department	
Email:	
Telephone:	

2. Details of Study

Full title of study:	
SHU Reference Number	
Funder Reference	
Research sponsor:	

3. Nature of Event

Please categorise this event, ticking all appropriate options:

Death		Persistent or significant disability or incapacity	
Life-threatening		Congenital anomaly or birth defect	
Hospitalisation		Other	

Sheffield Hallam University

4. Circumstances of Event

Date of SAE:	
Location:	
Description of the circumstances of the event: *(Detailed report may be attached)*	
Assessment of the implications, if any, for the safety of study participants and how will these be addressed?	

5. Record of Actions Taken

Actions		**Completed by:**	**Date**
1			
2			
3			

No further action required: Yes / No If yes, please specify below

6. Declaration

Signature of Principal Investigator:	
Print name:	
Date of submission:	

Receipt of the report will be acknowledged by Research and innovation Services

Date Received in RIS:	
Received by:	
Actioned by:	