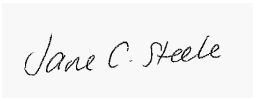
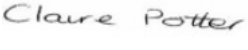
RESEARCH & INNOVATION SERVICES

UNIVERSITY OF SUSSEX

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Management of Adverse Events

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	Name	**Designation**	**Signature**	**Date**
Author:	Jane Steele	Research Ethics, Integrity and Governance Senior Manager		05-Oct-2026
Reviewer:	Caroline Gordon	Head of Research Ethics, Integrity and Governance		12-Oct-2026
Approved by:	Claire Potter	Director of Research and Innovation Services		09-Oct-2026

1. Purpose and scope

This standard operating procedure (SOP) describes the procedures for the assessment, recording and reporting of Adverse Events (AEs). Adherence to this SOP will ensure that appropriate action is taken to protect participant safety and minimise harm.

It is applicable to all investigators at the University of Sussex (including Brighton and Sussex Medical School) involved in research studies sponsored by the University of Sussex with the exception of Suspected Unexpected Serious Adverse Reactions (SUSARs) for Clinical Trials of Investigational Medicinal Products or Clinical Investigations of a Medical Device that are managed by an accredited Clinical Trials Unit (CTU). These studies should adhere to relevant SOPs implemented within the CTU.

University of Sussex sponsored studies conducted within the NHS should also adhere to NHS Trust policies and procedures.

This SOP is expected to be used in conjunction with the relevant University of Sussex policies and the Code of Practice for Research.

2. Abbreviations

AE	Adverse Event
CI	Chief Investigator
IMD	Clinical Investigation of a Medical Device
CTU	Clinical Trials Unit
SAE	Serious Adverse Event
SOP	Standard Operating Procedure
SUSAR	Suspected Unexpected Serious Adverse Reaction

3. Background

AEs may occur during study conduct for reasons beyond the control of the researcher, as well as through errors or mistakes made during research activity. They may be identified by research team members, during monitoring or audit, or by direct contact from the participant(s).

As a sponsor of research studies falling under the UK Policy Framework for Health and Social Care Research, the University of Sussex is responsible for ensuring that AEs are properly assessed, documented, and reported in alignment with the HRA and MHRA requirements. This responsibility is also described in the ICH Guidelines for Good Clinical Practice E6(R3).

The level of AE reporting, and procedures for their assessment and reporting, should be clearly specified in the study protocol. It is important to assess any AE for seriousness, relatedness, and expectedness. Reporting requirements may differ depending on the nature of a research study and the participant population.

For the purposes of this SOP, the following definitions apply:

Adverse Event (AE)	Any unfavourable sign, symptom or disease which does not necessarily have a causal relationship with a study intervention or procedure.

Serious Adverse Event (SAE)	An adverse event (AE), is defined as serious if it meets at least one 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 abnormality or birth defect • Is considered clinically significant by the investigator
Suspected Unexpected Serious Adverse Reaction (SUSAR)	An adverse reaction that meets three criteria: • Related • Unexpected • Serious
Relatedness	An assessment of an event for a causal link to a research intervention or procedure: **Unrelated** – No evidence of a causal relationship (unrelated to a study intervention or procedure). **Related** – Evidence of a causal relationship (related to a study intervention or procedure).
Expectedness	An assessment of whether an event could have been anticipated based on existing study information as outlined in the protocol. **Expected** – Consistent with known and documented risks as outlined in the protocol. **Unexpected** – Not consistent with known and documented risks as outlined in the protocol.

4. Responsibilities

☐ The Chief Investigator (CI) has responsibility for:

- Reporting AEs to the sponsor and relevant external regulatory bodies and in adherence to the relevant reporting requirements.
- Ensuring that the assessment, recording and reporting requirements for AEs is clearly documented in the study protocol.
- Ensuring that all research team members are appropriately trained in how to record and report AEs in accordance with the protocol (and that this training is documented).
- Ensuring that AEs/SAEs are assessed, recorded and reported appropriately within the required timeframes.

- Maintaining oversight of all AEs/SAEs throughout the study.
- For multi-site studies, reviewing AE assessments made by Principal Investigators or Local Collaborators and keeping them informed of relevant information about SAEs that could adversely affect participant safety.

☐ The Head of Research Ethics, Integrity & Governance must ensure that all SAEs are reported to the University of Sussex Health and Social Care Sponsorship Sub-Committee.

☐ All research team members must ensure that they are aware of procedures relating to the management of AEs, and the requirements for reporting them promptly.

☐ All investigators at the University of Sussex (including Brighton and Sussex Medical School) involved in research studies sponsored by the University of Sussex must follow this SOP.

5. Procedure

5.1. Study-specific requirements

5.1.1. During development of the study protocol, the CI must decide on the requirements for AE reporting based on the risk of the study to the participants and the study objectives (and in accordance with applicable regulations and guidance), noting that reporting requirements are likely to differ based on the relatedness to the study and expectedness, see Point 5.3.

5.1.2. Procedures for the management of AEs and the requirements for assessment, recording and reporting, must be clearly documented in the study protocol.

5.1.3. The CI should consider the development of forms or tools to record details of any AE, and outcomes from the assessment of seriousness, relatedness and expectedness. However, SAEs must be reported to the sponsor using the Serious Adverse Event Report Form (Appendix A).

5.1.4. The CI must ensure that all research team members are appropriately trained in how to manage AEs in accordance with the protocol (and that this training is documented), prior to the start of recruitment.

5.2. Immediate actions to be taken when an Adverse Event is identified

5.2.1. Once identified, and as soon as possible, the CI must ensure that:

- ☐ Appropriate action has been taken to ensure the safety and well-being of the participant(s) affected.
- ☐ Circumstances of the AE are reviewed and documented.
- ☐ An assessment of seriousness, relatedness and expectedness is made (according to the definitions presented on page 3 of this document) and reported to the sponsor where appropriate, see Point 5.3.
- ☐ Details of the AE, including outcomes of the assessments and any corrective and/or preventative actions are recorded.
- ☐ The record is retained in the Study Master File and/or Site File.

5.3. Reporting of Serious Adverse Events

5.3.1. Specific reporting requirements exist when an AE is assessed to be **serious**, **related** to a study intervention or procedure, and **unexpected**.

- ☐ The Serious Adverse Event Report Form (Appendix A) must be completed and returned to the **sponsor within 48 hours** of the CI being made aware of the event.
- ☐ The SAE must also be reported to the approving **NHS REC within 15 days** of the CI being made aware of the event using the Non-CTIMP safety report to REC form.

5.4. Additional reporting requirements for studies involving medical devices

This section applies to trials of medical devices that are non CE-marked, or CE marked but are being used outside of the intended use(s) covered by the CE mark.

5.4.1. The following must be reported to the MHRA using the MORE portal as soon as possible **as soon as possible**:

- ☐ Any SAE whether initially considered to be device related or not.
- ☐ Any Investigational Medical Device Deficiency that might have led to a SAE if suitable action or intervention had not been taken.
- ☐ New findings/updates in relation to already reported events.

5.5. On-going monitoring and oversight of Serious Adverse Events

5.5.1. SAEs that do not result in death must have ongoing monitoring by the clinical or research teams to detect any escalation until the end of the event.

5.5.2. For multi-site studies, the CI must:

- ☐ Maintain oversight of all SAEs via regular reports from study sites.
- ☐ Inform all Principal Investigators or Local Collaborators at local sites of relevant information about SAEs that could adversely affect the safety of subjects.

6. Related documents

N/A

7. References

University of Sussex Research Ethics Policy

Code of Practice for Research

UK Policy Framework for Health and Social Care Research

ICH Guidelines for Good Clinical Practice E6(R3)

8. Appendices

APPENDIX A. Serious Adverse Event Report Form

VERSION HISTORY

Version number	Effective date	Reason for update
1.0	12-Oct-2026	Original version

APPENDIX A. Serious Adverse Event Report Form

The form starting on the following page must be used to report SAEs to the sponsor (researchsponsorship@sussex.ac.uk) **within 48 hours** of the CI being made aware of the event.

Delete pages 1-7 of this document before completing the form.

SECTION 1: STUDY DETAILS	
Sponsor reference:	Click or tap here to enter text.
Chief Investigator:	Click or tap here to enter text.
Long study title:	Click or tap here to enter text.
Short study title:	Click or tap here to enter text.
IRAS ID:	Click or tap here to enter text.
REC approval reference:	Click or tap here to enter text.

SECTION 2: SERIOUS ADVERSE EVENT DETAILS	
Name or ID of site:	Click or tap here to enter text.
Date of onset:	Click or tap to enter a date.
Date identified:	Click or tap to enter a date.
Name of individual who identified the SAE:	Click or tap here to enter text.
Role of individual who identified the SAE:	Click or tap here to enter text.
ID of participant(s) affected:	Click or tap here to enter text.
Briefly describe the SAE:	Click or tap here to enter text.
Briefly describe the immediate corrective actions that have been taken:	Click or tap here to enter text.
Briefly describe the preventative actions that will be been taken:	Click or tap here to enter text.

SECTION 3: ASSESSMENT		
Please confirm which is the applicable Serious Adverse Event criteria: *(Please check one option)*	☐	Death
	☐	Life threatening
	☐	Hospitalisation, or prolongation of existing hospitalisation
	☐	Persistent or significant disability or incapacity
	☐	Considered clinically significant
	☐	Other

Please confirm that you believe the SAE to be **related** to a study intervention or procedure:	Choose an item.
Please confirm that you believe the SAE to be **unexpected** (i.e., not consistent with known and documented risks as outlined in the protocol):	Choose an item.
Name of individual carrying out the assessment:	Click or tap here to enter text.
* Role of individual carrying out the assessment:	Click or tap here to enter text.
Signature:	
Date:	Click or tap to enter a date.

**** If anyone other than the Chief Investigator has carried out the assessment and completed this section, Section 4 'Chief Investigator Validation' must be completed.***

SECTION 4: CHIEF INVESTIGATOR VALIDATION	
I am in agreement with the assessment recorded in the section above:	Choose an item.
Name:	Click or tap here to enter text.
Signature:	
Date:	Click or tap to enter a date.
If you are NOT in agreement with the assessment recorded above, please conduct your own assessment and complete Section 5 'Chief Investigator Assessment'.	

SECTION 5: CHIEF INVESTIGATOR ASSESSMENT		
SAE criteria: (Please check one option)	☐	Death
	☐	Life threatening
	☐	Hospitalisation, or prolongation of existing hospitalisation
	☐	Persistent or significant disability or incapacity
	☐	Considered clinically significant
	☐	Other
Do you believe the SAE to be **related** to a study intervention or procedure?		Choose an item.
Do you believe the SAE to be **unexpected** (i.e., not consistent with known and documented risks as outlined in the protocol)?		Choose an item.
Name:		Click or tap here to enter text.
Signature:		
Date:		Click or tap to enter a date.

Return the completed form to researchsponsorship@sussex.ac.uk within 48 hours