Standard Operating Procedure	Lancaster University

Title: Adverse Event Procedure (non-CTIMP)

SOP Reference: HSCR-SOP003 **Version and Date: V1.0** **Superseded SOP (version and date):** NA	**Date Effective From:** **Review Cycle: 2 Years** **Date of Next Review: 2027**

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Signature: **Date:**

Document History

Version	Date	Reasons for Change
1.0	16/07/2025	New document

1. BACKGROUND

1.1 Adverse events (AE's) and serious adverse events (SAE's) that occur during a research project must be appropriately identified, assessed, recorded, and reported to protect participants and minimise harm.

1.2 As a sponsor of Health and Social Care Research, Lancaster University is responsible for:

- Ensuring safety reporting systems are in place;
- keeping records of reported AE's and assessing their seriousness, relatedness, and expectedness;
- collaborating with Chief Investigators (CIs) on AE/SAE categorisation and risk review;
- reporting safety issues to relevant University committees;
- supporting researchers in reporting to NHS Research Ethics Committees (NHS REC) and regulators; and
- submitting annual safety reports to University oversight bodies.

1.3 CI's are responsible for the scientific and safety aspects of their studies. The sponsor delegates the following duties to CI's:

- Accurately recording and reporting AE's and SAE's in medical records or case report forms (CRF's);
- categorising AE's and SAE's with sponsor input and ensuring participant safety;
- reporting SAE's to the sponsor within 48 hours;
- reporting related and unexpected SAEs to the NHS REC within 15 days using the appropriate form; and
- submitting annual safety reports where required to the relevant regulatory authorities.

2. PURPOSE AND SCOPE

2.1 This Standard Operating Procedure (SOP) outlines the process for identifying, documenting, managing, and reporting AE's and SAE's for Lancaster University-sponsored studies falling under the UK Policy Framework for Health and Social Care Research.

2.2 The SOP enables Lancaster University to identify serious and non-serious AE's in studies for which it is responsible; assess whether events are study-related; and ensure appropriate action is taken to minimise harm and prevent recurrence.

2.3 This SOP applies to all research staff involved in sponsored studies; the Lancaster University Clinical Research Governance Team (CRGT); and the Health and Social Care Research Sponsorship Committee who are all responsible for safety reporting.

3. DEFINITIONS

Adverse Event (AE) [1]	In relation to a study participant, it can be described as any unfavourable and unintended sign, symptom or disease temporally associated with participation in the research project. Adverse events may occur for any number of reasons beyond the control of the researcher, as well as through errors or mistakes made during research activity.
Serious Adverse Event (SAE) [3]	A serious adverse event* is an untoward occurrence during participation in a research study that meets at least one of the following criteria: • Results in death • Is life threatening • Requires hospitalisation or prolongation or existing hospitalisation • Results in persistent or significant disability or incapacity • Consists of a congenital abnormality or birth defect • Is considered medically significant by the CI
Relatedness	Relatedness is an assessment of an event for a causal link to the research intervention or procedures; and should be determined by the CI/PI/ or a designated medically qualified individual, agreed by the sponsor. The following definitions can be used: • **Unrelated** – no evidence of a causal relationship, unrelated to a study event or procedure • **Related** – evidence of a causal relationship, related to a study event or procedure
Expectedness	Expectedness is an assessment of whether an AE or SAE could have been anticipated based on existing study information as outlined in the protocol, summary of product characteristics, or study documents. This should be assessed by the CI/PI or a medically qualified expert agreed by the sponsor: • **Expected** – Consistent with known and documented risks as per the protocol • **Unexpected** – Not consistent with known and documented risks as per the protocol
Chief Investigator (CI)	The lead researcher with overall responsibility for the design, conduct, and reporting of a research project. Outside the UK, this may be termed "Coordinating Investigator."
Principal Investigator (PI)	The person responsible for conducting the research at a particular site. In single-site studies, the CI may also act as the PI.

*Note: The definition of serious may differ depending on the project and participant demographic. All researchers are required to define serious adverse events within the protocol if they feel that the above definition is not applicable to their participant cohort.

4. PROCEDURE

4.1 Identifying Adverse Events (AE's) and Serious Adverse Events (SAE's)

4.1.1 AE's and SAE's may be identified by site research or clinical staff, during monitoring or audit, or following direct contact with the participants. The sponsor or central research team may also become aware of AE's or SAE's from the central monitoring and audit, or by a participant directly contacting them.

4.1.2 All research staff must be aware of AE procedures and their responsibility to report events promptly.

4.2 Categorising and managing SAE's and AE's*

4.2.1 Following identification, all AEs must be assessed for seriousness, relatedness, and expectedness.

4.2.2 Where identified at research sites, the Principal Investigator (PI) is responsible for categorising events using the AE Decision Tree (Appendix 5.2) and study protocol; where identified outside of the research site, or at sites without a PI, the Chief Investigator (CI) assumes this responsibility.

4.2.3 The PI or CI (in line with responsibility as outlined in 4.2.2) is also responsible for deciding the most appropriate course of action when an AE or SAE has been highlighted, and any management of the participant until the end of the event.

4.2.4 Both AE's and SAE's that do not result in death must have ongoing monitoring by the clinical or research teams to detect any escalation; and the CI must maintain oversight of all AEs/SAEs via regular reports from study sites-regardless of where the event was identified.

4.2.5 When the CI receives an SAE report from a research site, they must review and confirm the PI's categorisation or upgrade it if necessary (but not downgrade). Both original and revised assessments must be documented.

4.3 Documenting and Reporting AE's

4.3.1 All AE's must be documented in full using the Adverse Event Report Form (HSCR-FORM006) as soon as possible.

4.3.2 AE's identified at site are to be documented as follows:

- Sections 1–3 of the AE report form (HSCR-FORM006) must be completed by the staff member who identified the event;
- Sections 4–6 of the AE report form (HSCR-FORM006) must then be completed by the PI
- The AE must also be recorded in the participant's medical/care record, the report form saved in the Investigator Site File (ISF) and then shared with the CI and sponsor quarterly or upon request.

4.3.3 AE's identified outside a research site are to be documented as follows:

- Sections 1–3 of the AE report form (HSCR-FORM006) must be completed by the staff member who identified the event;
- Sections 4–6 of the AE report form (HSCR-FORM006) must be completed by the PI

- The AE report form (HSCR-FORM006) is to be stored in the participant's records and the Trial Master File (TMF) and shared with the site if participant was recruited there with advice on any actions provided.

4.3.4 While non-serious AE's have no external reporting deadlines, they must be retained in the TMF, and submitted to the sponsor quarterly for review by the Health and Social Care Research Sponsorship Committee.

4.3.5 The Clinical Research Governance Team (CRGT) must submit all AE summaries for committee review annually.

4.4 Documenting and Reporting of Serious Adverse Events (SAEs)

4.4.1 All SAE's must be reported to the sponsor within 48 hours of awareness and documented on the Adverse Event Report Form (HSCR-FORM006).

4.4.2 Initial reporting must include a minimum dataset of: the event description, Participant ID, and Reporter name-full documentation must follow as soon as possible.

4.4.3 Where an SAE has been identified at site, they should be documented and reported as follows:

- Sections 1–3 of the AE Report Form (HSCR-FORM006) should be completed with at least the minimum dataset outlined in 4.4.2 by the staff member who identified the SAE, then reported directly to the PI in the first instance.
- Sections 4–6 of the AE report form (HSCR-FORM006) must include at least the minimum data set outlined in 4.4.2 completed by the PI and returned to the Chief Investigator (CI) within 48 hours.
- Site staff must also record the event including a description, even start time, duration of the event, severity, actions taken, and outcome, in the participant's medical or care records.
- The report form must be stored in the ISF.

4.4.4 Upon receiving a completed form, the CI should validate the details, complete any missing items from the minimum dataset, and return the sponsor within 48 hours of receiving it.

4.4.5 Should there be any follow up actions, the CI must instruct the research site to carry them out where necessary.

4.4.6 All additional details must be completed on the AE report form, as soon as the details become available.

4.4.7 SAE's identified by the central research team, sponsor, or monitor should be documented and reported as follows:

- The individual who became aware of the event should complete sections 1 to 3 of the AE report form (HSCR-FORM006) including the minimum dataset outlined in 4.4.2, and share it with the CI within 24 hours.

- Within 48 hours of becoming aware of the event, the CI or research team must share at least the minimum set of data required with the sponsor via sponsorship@lacaster.ac.uk.
- The CI is required to categorise the SAE, determine any actions that are required, update and sign the AE report form (HSCR-FORM006), before sharing the updates with the sponsor.
- The CI is then responsible for informing the research site (if participant is linked to a site), providing the completed form for local records, and communicating any necessary actions.

4.4.8 If a study has favourable NHS REC opinion and the SAE is: Serious, Unexpected, and Related, then a non-CTIMP Safety Report to REC form must be completed and shared with the sponsor and then sent to the NHS REC who offered favourable opinion within 15 working days.

4.4.9 Studies with no NHS REC reporting requirement, are only required to submit the AE report form (HSCR-FORM006) to the sponsor within 48 hours of being made aware of the SAE.

4.4.10 As a result of the SAE, the sponsor may require adjustments to the protocol or risk assessment.

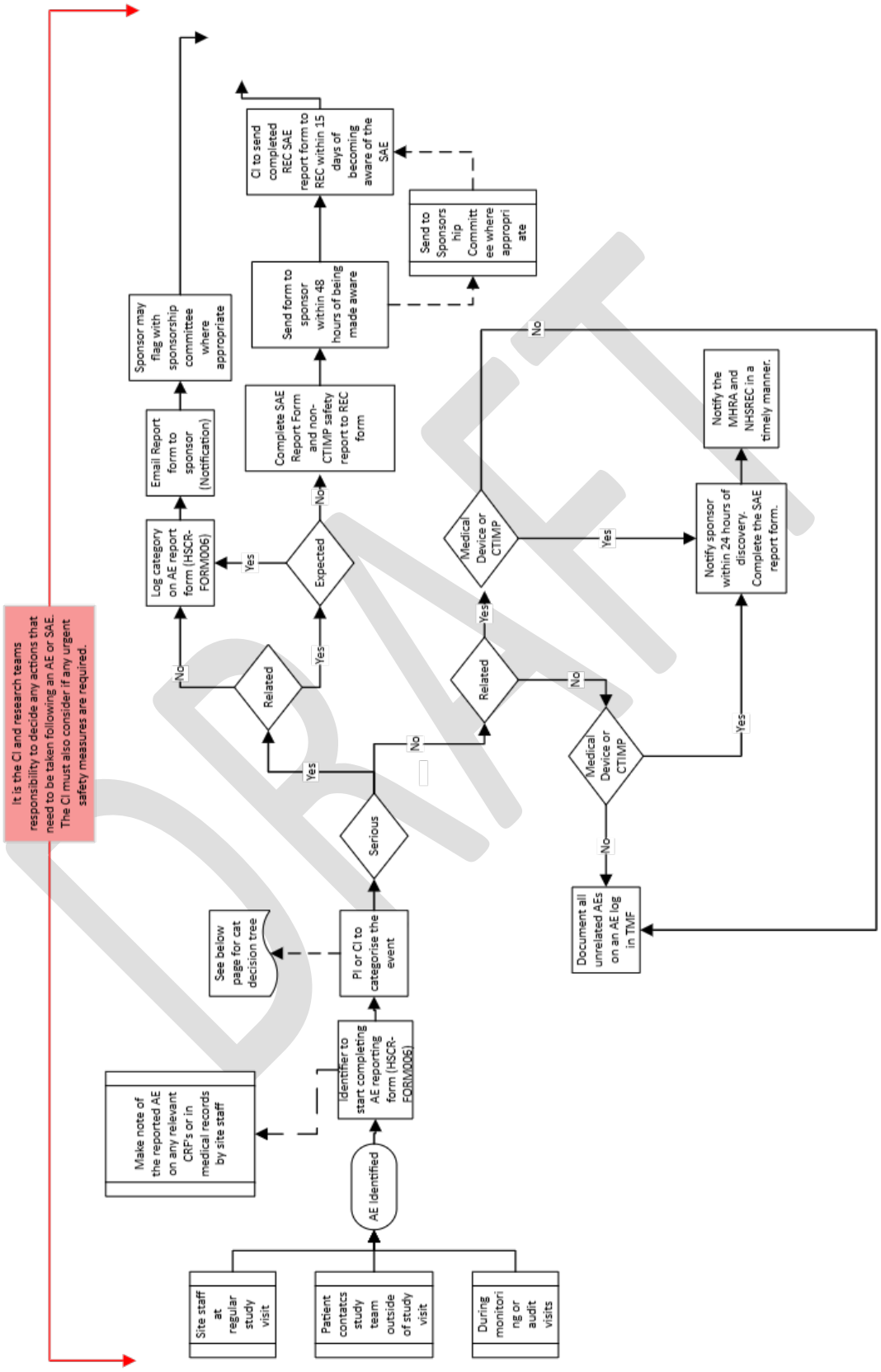
4.4.11 The Clinical Research Governance Officer will notify the Health and Social Care Research Sponsorship Committee of SAEs that are serious, related, and unexpected within 48 hours of being made aware; and quarterly for all other SAEs and AEs.

4.4.12 Additional independent assessment may be mandated by the Health and Social Care Sponsorship Committee, if deemed necessary.

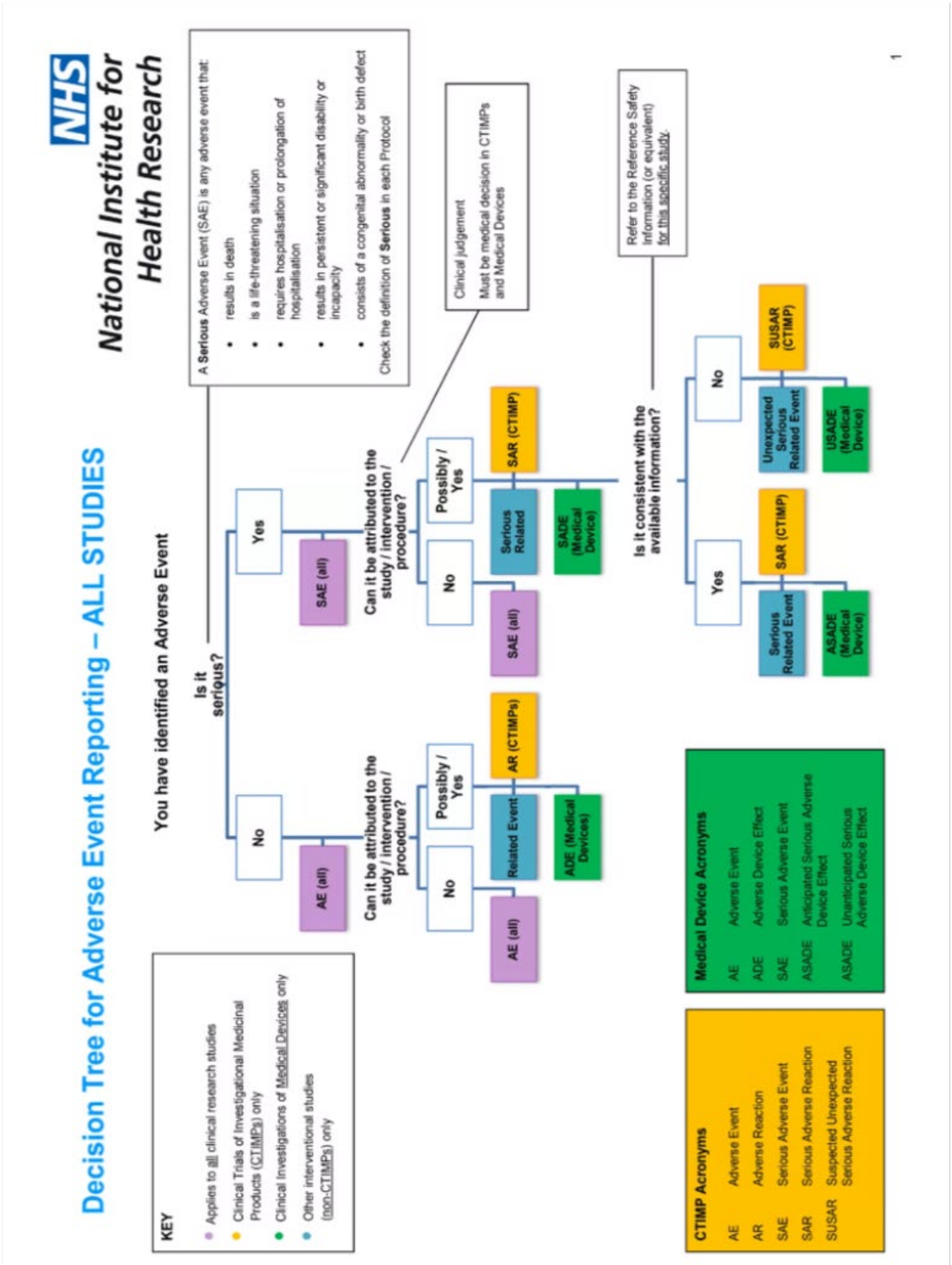
4.4.13 All researchers should also check the Health and Safety reporting requirements for adverse events with OED. Health and Safety England (HSE) have reporting requirements for events and near misses that occur both within and outside of research that cause physical harm to humans. For more information, please contact safetyoffice@lancaster.ac.uk.

5. Appendices

5.1 HSCR-FLOW006 Adverse Events Documenting and Reporting Flow Chart



5.2 NIHR Decision Tree for categorising and reporting adverse events



5.3 HSCR-FORM006 Lancaster University Adverse Event Report Form Template*

***This form can also found on the webpage document repository**

Form Title:	Adverse Event Report Form	Lancaster University
Form Ref.:	HSCR-FORM006	

This form must be completed for adverse events occurring in research studies sponsored by Lancaster University. If the adverse event is deemed to be serious or related, please save and return this form to sponsorship@lancaster.ac.uk. The email should come from or be copied to the Chief Investigator's work email address. If the event is deemed to be adverse, but not serious then please store the form in the Investigator Site File (ISF) or Trial Master File (TMF) and return to the sponsor when requested.

Section 1 – Study and Adverse Event Details	
Full title of research study	
IRAS ID	
Site ID or Name	
Principal Investigator Name	
Adverse Event ID (SITEIDSA00X or SITEIDSAE00X)	
Start date of Adverse Event	Click or tap to enter a date.
Start time of Adverse Event	
End date of Adverse Event	Click or tap to enter a date.
End time of Adverse Event	
Date of Form Completion	Click or tap to enter a date.

Section 2 – Adverse Event Details

Section 3-Action Taken

Section 4-Principal Investigator Assessment of Seriousness (If identified by/at NHS site)	
Serious Adverse Event?	Serious Adverse Event ☐
	Adverse Event ☐
Serious Adverse Event Criteria (if applicable)	Death ☐
	Life Threatening ☐

	Hospitalisation or prolongation of existing hospitalisation ☐
	Persistent or significant disability or incapacity ☐
	Other (please specify) ☐

Section 5 – Principal Investigator Assessment of Expectedness and Relatedness (If identified by/at NHS site)	
Expectedness	Expected ☐
	Unexpected* ☐
Relatedness	Related * ☐
	Unrelated ☐
***Please note if your study had National Research Ethics Service favorable opinion, and the AE is serious, related and unexpected, then you will need to complete a non-CTIMP Safety Report to REC form, which can be found on the HRA webpage. If required, please ensure that this is included with the submission to the Clinical Research Governance team.**	

Section 6 – Principal Investigator Signature (If identified by/at NHS site)	
Principle Investigator Signature	
Print Name	
Date	Click or tap to enter a date.

Section 7-Chief Investigator Validation (If identified by/at NHS site)	
I confirm I agree with the categorisation above and am happy with the actions taken by the PI. (if selected you do not need to complete section 8 onwards. And should sign the declaration in section 7) ☐	**I disagree with the categorisation above and would like to complete my own assessment.** (if selected, please proceed to section 8 onwards) ☐
Chief Investigator Signature	
Print Name	
Date	Click or tap to enter a date.

Section 8-Chief Investigator Assessment of Seriousness (if identified by the central research team/ if different from the PIs categorisation above)	
Serious Adverse Event?	Serious Adverse Event ☐
	Adverse Event ☐
Serious Adverse Event Criteria (if applicable)	Death ☐
	Life Threatening ☐
	Hospitalisation or prolongation of existing hospitalisation ☐
	Persistent or significant disability or incapacity ☐
	Other (please specify) ☐

Section 9 – Chief Investigator Assessment of Expectedness and Relatedness (if identified by the central research team/ if different from the PIs categorisation above)	
Expectedness	Expected ☐
	Unexpected* ☐
Relatedness	Related * ☐
	Unrelated ☐
***Please note if your study had National Research Ethics Service favorable opinion, and the AE is serious, related and unexpected, then you will need to complete a non-CTIMP Safety Report to REC form, which can be found on the HRA webpage. If required, please ensure that this is included with the submission to the Clinical Research Governance team.**	
Section 10– Chief Investigator Comments (if identified by the central research team/ if different from the PIs categorisation above)	
This can include any comments about the SAE or any action you will or have taken. This could also include any requests for the research site PI to undertake any further action.	
Section 11-Chief Investigator Signature	
Chief Investigator Signature	
Print Name	
Date	Click or tap to enter a date.
FOR SPONSOR OFFICE USE ONLY	
Received by	
Date received	
Date sent to sponsorship committee	
Feedback from committee	