# Research & Innovation Office

Standard Operating Procedure

St Luke's Hospice

Recording & Reporting of Adverse Events

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| **Date Effective** | 23/06/2025 | **Author** | Clare Pye<br>Research & Innovation Manager |
| **Related SOP's:**<br>Research Policies & procedures. V3. Dated 21/01/2025<br><br>SLHSOP003. Documenting Source data. V1 dated 23/06/2025<br><br>SLHSOP004 – Maintaining a study site file. V1 dated 23/06/2025<br><br>SLHSOP005 – Reporting Protocol & GCP Deviations/Violations. V 1 dated 23/06/2025 | | **Document Summary:**<br>Describes the processes for recording and reporting adverse events for non-CTIMPs (Clinical Trials of Investigational Medicinal Products). | |
| **Approved by (name & Role)** | Dr Paul Taylor<br>Head of Research - SLH | **Date** | 23/06/2025 |
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Standard Operating Procedure: Research & Innovation Office

## Acronyms

**CI –** Chief Investigator
**PI-** Principal Investigator
**CTIMP -** Clinical Trial of an Investigational Medicinal Product
**GCP**- Good Clinical Practice
**SOP –** Standard Operating Procedure
**R&IO –** Research & Innovation Office
**SLH –** St Luke's Hospice
**TMF -** Trial Master File
**CRFs -** Case Report Forms

**ISF -** Investigator Site File
**SAE** - Serious Adverse Event
**AE** – Adverse Event
**TMG** – Trial Management Group
**TSC**- Trial Sterring Committee
**DMEC** – Data Monitoring & Ethics Committee

## 1. Introduction

The UK Policy Framework for Health & Social Care Research requires that the principles of Good Clinical Practice (GCP) are applied to all NHS research involving patients and that the safety of research participants is given priority at all times. While St Luke's Hospice is not an NHS organisation our policies and procedures align with this framework.

## 2. Purpose

To describe the responsibilities and processes related to the identification, assessment, recording, and reporting of adverse events occurring in research studies (including clinical trials). The Hospice does not currently provide sponsorship to research studies but does host them. For hosted studies, study teams should adhere to the Sponsor SOP concerning adverse events. Researchers should initially familiarise themselves with the entire contents of this SOP. However, the document is primarily designed as a practical reference guide to be used alongside the study Protocol.

## 3. Roles and responsibilities

All SOPs can be accessed on the Hospice website.

The Research & Innovation Office (R&IO) is responsible for managing Hospice R&I SOPs including their approval, dissemination and archiving. All Hospice R&I SOPs are available and published on the Hospice website.

### Duties within the Organisation

It is the responsibility of the SLH R&I Office to make hospice R&I SOPs available to all research active staff working on hospice approved research studies.

It is the responsibility of the study Chief Investigator (CI) or local Principal Investigator (PI) to ensure that the research team know where to access up-to-date copies of SLH R&I SOPs. This and other responsibilities are delegated to the lead investigator as stated in the Confirmation of Capacity and Capability approval letter. It is the personal responsibility of all staff to follow the procedural documents as agreed between the hospice, PI/CI, and sponsor (if different from SLH). The R&I Office is responsible for managing hospice R&I SOPs including their approval, dissemination, and archiving.

## 4. Definitions

### Adverse Event (AE)

Any untoward, unfavourable, and unintended medical occurrence in participants to whom a study procedure is administered whether or not considered related to the investigational intervention.

AEs should be assessed for their potential seriousness and then assessed for relatedness to any study procedures, severity, and expectedness. Unless exempted by the approved Protocol, an adverse event is classified as a Serious Adverse Event (SAE) if the occurrence:

- Results in death
- Is life-threatening*
- Requires inpatient hospitalisation or prolongs existing hospitalisation
- Results in persistent or significant disability/incapacity.

*Life-threatening in the definition of a Serious Adverse Event (SAE) refers to an event in which the participant was at risk of death at the time of the event; it does

not refer to an event which hypothetically might have caused death if it were more severe.

The Protocol may also define certain additional events that should be considered as Serious Adverse Events (SAEs) for the purposes of the trial but do not fall into the categories listed above. Conversely, the Protocol may specify certain events that fall into the categories listed above that should not be considered as SAEs for the purposes of the trial.

Professional judgement should be exercised in deciding whether an adverse event/reaction is serious in other situations. Adverse events that are not immediately life-threatening or do not result in death or hospitalisation, but may jeopardise the participant, or may require intervention to prevent one of the other outcomes listed in the definition above, should also be considered serious. Events that qualify as SAEs should be made clear in the Protocol.

## Relatedness

The Chief Investigator (CI) should assess SAEs for potential relatedness to any study procedures and judge whether the event could have a reasonable causal relationship to any study procedures conducted.

An SAE can be classified as:

- not related
- possibly related
- probably related,
- definitely related.

This decision should be recorded on the SAE form. If the CI is unsure whether the event is related, they should seek advice from the Trial Steering Committee (TSC) and Data Monitoring and Ethics Committee (DMEC).

## Severity

The term "severe" is often used to describe the intensity (clinical severity) of a specific event. This is not the same as "serious", which is a regulatory definition based on participant/event outcome or actions taken to mitigate the event. For example, a headache may be severe but not serious, while a minor stroke is serious but may not be severe. Criteria for grading severity should be included in the Protocol.

The following is an example:

Mild: asymptomatic or mild symptoms, diagnostic observations only, no intervention indicated. Symptoms do not interfere with everyday activities/functioning.

Moderate: an event that is sufficiently discomforting to interfere with normal everyday activities. Minimal, local, or non-invasive intervention indicated.

Severe: an event that prevents normal everyday activities. Medically significant but not immediately life-threatening. Hospital or prolongation of hospitalisation indicated.

## Expectedness

When an AE has been determined to be related to the study procedure, its expectedness must be assessed. Events which are not considered to be related to the study procedure do not need to be assessed for expectedness. The Protocol must define events which are expected for the study procedure and must be used to assess whether events are expected.

Expected events are not events which cause no concern for the investigator.

## Incident

An event or circumstance that could have resulted or did result in unnecessary damage, loss, or injury such as physical or mental injury to an individual.

## 5. Specific to this SOP

Adverse event assessment, recording, and reporting are formally the responsibility of CI/PI or can be delegated further to the research team and a record of agreed roles must be recorded on the Delegation Log. All documents capturing delegation of responsibilities should be kept in the Trial Master/Site File for audit purposes, and to ensure that the hospice's responsibilities are being appropriately met.

At each study visit, or as otherwise specified in the Protocol, the CI, PI, or delegate, is responsible for eliciting details of any adverse events (AEs) from participants that may have occurred since the previous study visit and ensuring that these are evaluated appropriately.

The CI/PI is responsible for assessing the 'relatedness' of an event and signing off the adverse event report. Where required, the Data Monitoring and Ethics Committee (DMEC) and Trial Steering Committee (TSC) may assist with determining relatedness and identifying trends. If the CI/PI is not available to review and sign the report, this responsibility can be fulfilled by the another suitably qualified member of the study team provided this is listed on the delegation log. The CI must inform the Sponsor of these arrangements prior to going on leave.

AE's must be recorded in the participant's medical records and a Case Report Form (CRF). Serious Adverse Events (SAEs) involving SLH hospice service users must be reported to the sponsor within ***24 hours*** of the study team becoming aware of the event, unless stated otherwise in the Sponsor approved Protocol.

### Classification of Adverse Events

For hospice studies, the sponsor expects the CI/PI to carry out the initial assessment of the relatedness of SAEs, and expectedness of related SAEs (in accordance with the Protocol), on behalf of the Sponsor. The final decision regarding the classification of the SAE should lie with the CI, TSC, and/or DMEC.

## Recording and Reporting of Adverse Events.

1. Check the Protocol to determine if the event needs to be recorded and/or reported. For exempted events, act as specified in the Protocol. If not, proceed as follows.
2. If required by the Protocol, record the Adverse Event on the case report form (CRF). Ensure the following information is clearly documented in the participant's medical record:
    - Whether the event has been observed by a study team member or reported by the participant
    - The date and, if possible, the time of the onset of the event
    - If completely resolved, the duration of the event
    - The severity of the event (not to be confused with seriousness – see definitions above)
    - The assessment of the seriousness, relatedness, and expectedness as determined by the CI/PI
    - Any treatment/medication given for the event, including dates
    - The outcome of the event.

3. Add the event to the study adverse event log in the Trial Master/Site File. This log should be made available for review by the TMG, TSC, DMEC, or Sponsor, as required.

4. Take any other action specified by the Protocol (e.g. unblinding).

5. The CI/PI must assess the event against the Protocol to determine the seriousness, relatedness, severity, and expectedness of the event.

6. For events classified as Serious Adverse Events, complete the Sponsor SAE form within ***24 hours*** of becoming aware of the event and follow the Protocol for detail of how to submit to the relevant parties. The Sponsor's SAE form must be used to report SAEs. Where the Sponsor approved Protocol differs from this SOP, the Protocol takes precedence for determining next steps.

7. Serious Adverse Events forms should also be sent to the R&I Office, quoting the hospice project reference number and IRAS number. The R&I Office keeps a register of Serious Adverse Events, reviews each event, and reports relevant events to regulatory bodies as required.

8. If the event is ongoing at the time of completing the initial report, it should be followed up and documented in the participant's medical record at subsequent study visits until resolved, returned to baseline, or stabilised. AEs that are ongoing on completion of the study should be followed up as required by the Protocol and as clinically indicated. For SAEs, the 'Follow Up' section of the existing SAE report should be completed and sent to the R&I Office.

For Related and Unexpected SAEs, follow these further instructions:

i. The CI or study Sponsor must complete and submit a non-CTIMP safety report to REC form within 15 days of becoming aware of the event.
ii. ii. Any developing trends should be reported to the study's oversight committees (i.e., TSC, TMG, DMEC).

## Expedited Reporting

In addition to the reporting requirements outlined, safety issues also qualify for expedited reporting to the Ethics Committee where they might materially alter the current risk-benefit assessment of an experimental intervention; or are sufficient to consider changes in the administration of the intervention, or in the overall conduct of the trial.

Such events include:

- A significant hazard to the participant population
- A major safety finding from a newly completed study
- Recommendations of the R&I Committee and/or Trial Steering Committee, if any, where relevant for the safety of the participants. The Chief

Investigator/Principal Investigator must ensure that any such events are identified and reported in an expedited manner.

## References

Safety monitoring responsibilities as per the UK Policy Framework for Health and Social Care Research:

UK Policy Framework for Health and Social Care Research - Health Research Authority