Quality Control Document:

Internal Process Example for Serious Adverse Event (SAE) Handling

# Purpose

This document provides an example of how the process for serious adverse event (SAE) handling within a project team/coordinating centre could be documented. The use of this document is optional.

# Instructions

1. Remove this first instruction page.
2. Update the identifier in the header e.g. study/trial identifier or research group.
3. Update the footer, retaining the document reference information relating to this quality control document (QCD).
4. If using this document to generate a project-specific guideline, amend the text to fit in with the local processes. Instructions and guidance text are highlighted in red.
5. File the finalised version in the study/trial master file (S/TMF).

# Related documents

* UoB-AES-QCD-001 Serious Adverse Event (SAE) Form Template
* UoB-AES-QCD-003 Pregnancy Notification Form
* UoB-AES-SOP-001 Adverse Event Reporting

Note the UoB QMS documents can be found on the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT ([crct@contacts.bham.ac.uk](mailto:crct@contacts.bham.ac.uk)) and/or from the RGT ([researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk)).

# Internal process for SAE handling

## Introduction

This document describes the internal process for SAE handling for the <insert study/trial identifier>.

## Check for SAEs received

Sites are instructed to send their completed SAE forms by faxing <insert fax number, and office where the fax machine is located (preferably provide 2 fax numbers) >or by emailing <insert email address(es)>. Anyone who is potentially going to receive an SAE form, either by monitoring the identified fax machine(s) or being a nominated email recipient should be provided with the following instructions:

*Upon receipt of an SAE form for the* <insert study/trial identifier> *please inform <insert at least two contact names and/or job titles - whatever works best locally > directly.*

*If neither one of the named contacts is in the office, please send an email to both contacts and cc. <insert name of additional research team member>in the email, who will follow this up within the research-project team. Add a note on the form that <insert contact names> were informed by email, and put the form on the desk of either <insert contact names>.*

During the bank-holiday period, *<insert contact names>* will set up a system with site staff to ensure that any SAEs will be dealt with promptly. This may be, for example, a requirement for the site to call *<insert contact names>* on a pre-arranged phone number. The site will receive in writing what they are expected to do; a copy will be added to the study/trial master file (S/TMF).

## Receipt of SAE form

Upon receipt of an SAE form, the steps below should be followed by the project team.

1. Log the SAE on the SAE tracking sheet <it is strongly recommended to have a tracking sheet set up>.
2. Assign a unique code to the SAE, which will be <to be decided locally, e.g.: ‘Project Number – SAE number’>, add this to the SAE tracking sheet and onto the SAE form.
3. Reply to the site to confirm that the SAE form has been received, remember to include the SAE’s unique code. The confirmation may be sent to the site either by fax or email; if sent via fax, ensure that the sent fax is filed together with the SAE form.
4. Check that the SAE form has been fully completed and query any missing information and/or information that is not clear. This could be done by phone; in this case ensure the information is added to the SAE form (this may be on the original form or via a follow-up form) and that the site signs and dates to confirm the additional information is correct. The following information must be available in order to perform a clinical evaluation:

* research project number
* reason for reporting
* description or adverse-event term that prompted the report
* suspect drug/intervention information
* causality assessment.

## Evaluation

For this research project <insert name and role, this is typically the Chief Investigator but may be delegated> is responsible for reviewing the causality assessment and performing the expectedness assessment on SAEs. For times when <insert name> is absent, <insert names of deputies> who are medically qualified and have been trained to deputise for the named CI/delegate will be available to the project team. A list of deputies should also be added to the S/TMF.

The process of clinical evaluation is as outlined below.

1. The CI (or delegate) will review the causality assessment, and document this on the SAE form.

* Where the site PI (or delegate) has not performed a causality assessment, the project team will encourage them to do so.
* If the CI (or delegate) disagrees with the causality assessment as made by the site, the CI (or delegate) should ensure the differences are documented. Where the SAE is a suspected unexpected serious adverse reaction (SUSAR), both outcomes must be reported to the MHRA and REC. For further information, see point 3 below and refer to the Safety Reporting and Timeline section in the Adverse Event Reporting SOP (UoB-AES-SOP-001).

1. Where the SAE is assessed as being related to the trial/study, the CI (or delegate) will perform an expectedness assessment and document it on the SAE form.

* Use the reference safety information (RSI) as identified in the initial MHRA application form and/or in the latest development safety update report (DSUR).

1. <insert contact names> will categorise the SAE:

* if the SAE is unexpected and related to the trial/study, report it to the REC and MHRA, with a copy provided to the sponsor
* reporting timescales are:
* fatal/life threatening events: 7 days, any updates within 8 days
* all other events: 15 days, any updates within 8 days
* PIs should be informed in a timely fashion
* In all cases, file all documentation in the S/TMF.