Glasgow Clinical Trials Unit
Guideline 55.004A, version 2.0

COMPLETION GUIDELINES: GENERIC Non-CTIMP SERIOUS ADVERSE EVENT FORM, VERSION 1.1

PLEASE READ BEFORE COMPLETING THE NON-CTIMP SERIOUS ADVERSE EVENT (SAE) FORM

GENERAL INSTRUCTIONS.

The SAE form should be completed by an authorised member of the research team as recorded in the Delegation of Responsibilities Log.

Always use a black or blue ink ballpoint pen.

Ensure all entries are accurate, legible and verifiable with the source data.

If a correction is necessary, a single line should be drawn through the entire incorrect entry, the correct value entered. **ALL** corrections must be initialed and dated.

Complete boxes with a tick or cross.

Enter NA in any box if "Not applicable".

Fax the completed form to: Pharmacovigilance Office
Fax No: 0141 357 5588

The original form must be kept in the Study Site File.

For any enquiries regarding the completion of the SAE form, contact the Pharmacovigilance Office:
Email: pharmacovig@glasgowctu.org
Tel: +44(0)141 330 4744

Serious Adverse Event Form

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FOR RCB INTERNAL USE ONLY: This will be completed by the Pharmacovigilance Office

Complete Header Details on each page of the form: Sponsor Ref No/Study ID, Subject ID, Date of Report

Initial Report- tick if this is the first time you are sending notification of the event.

Follow up Report- tick if this is providing additional information for an event already reported.

Country where event occurred: enter UK or other country as appropriate.

Centre ID: add centre number

Subject Details

Initials:	Use format A-B or ABC
Date of Birth:	Complete as DDMMYYYY
Gender:	Tick as appropriate

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Serious Adverse Event

Diagnosis

Define the event in a few key words, such as a diagnosis or syndrome. If a definitive diagnosis is unavailable, record the primary symptoms.
Terms such as death, hospitalisation or a procedural name should not be used as event terms. For example:

- Subject was hospitalised for a cholecystectomy due to cholecystitis. The event term would be "Cholecystitis" not the procedure.
- Death is an outcome not an event term. The cause of death should be the event term.

SAE Onset date: enter the date the event became "serious" i.e. fulfilled at least one of the criteria for a Serious Adverse Event

Seriousness Criteria (Tick all that apply). See notes below

Resulted in death
Life threatening[1]
Hospitalisation / prolongation of hospitalisation[2].Provide date of admission and discharge
Persistent or significant disability or incapacity
Congenital anomaly / Birth Defect.
Other medically important condition[3]

Notes:
[1]Life-threatening in the definition of a serious adverse event or serious adverse reaction refers to an event in which the subject was at risk of death at the time of event; it does not refer to an event which hypothetically might have caused death if it were more severe.

[2] Hospitalisation is defined as an inpatient admission. Pre-planned hospitalisation e.g. for pre-existing conditions which have not worsened or for elective procedures, does not constitute a serious adverse event. If documented in protocol, certain hospitalisation can be excluded from the reporting process e.g. hospitalisation for chemotherapy, renal dialysis)

[3]Medical judgment should be exercised in deciding whether an adverse event/reaction is serious in other situations. Important adverse events/ reactions that are not immediately life-threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above should also be considered serious.

Relationship to Research Procedures: complete as appropriate

None: the SAE is not considered to be related to the research procedures

Possible: although a relationship to the research procedures cannot be completely ruled out, the nature of the event, the underlying disease, concomitant medication or temporal relationship makes other explanations possible.

Probable: the temporal relationship and absence of a more likely explanation suggest the event could be related to the research procedures.

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Definite: the known effects of the research procedures or challenge testing, suggest that the research procedure(s) is the most likely cause.

If related to Research Procedures (possibly, probably or definitely), Expectedness:
Complete as appropriate

Tick **Expected** if type of event is listed in the protocol as an expected occurrence.
Tick **Unexpected** if the type of event is **not** listed in the protocol as an expected occurrence.

Severity: this is a measure of the intensity of the event and the effect on the participant.

Mild: awareness of event but easily tolerated
Moderate: discomfort enough to cause some interference with usual activity
Severe: inability to carry out usual activity

Outcome: tick as appropriate

Recovered: If the SAE is a worsening of a pre-existing disease, "recovered" means a return to the intensity observed before the SAE.

Recovered with sequelae: The SAE has resulted in a permanent change to the patient's condition e.g. stroke with residual hemiplegia

Recovering: Continuing to improve but not yet recovered. Must be followed up until resolution and a follow up SAE report provided

Not recovered: Must be followed up until resolution and a follow up SAE report provided

Unknown: Must be followed up and a follow up SAE report provided

Fatal: Complete details in "If Resulted in Death" section

If "Recovered" or "Recovered with sequelae" ticked add:
Date of recovery: Enter the date the event ceased to be serious e.g. if hospitalisation-date of discharge. If the event is ongoing, a follow up report should be provided when there is a stop date or when significant changes occur.

If resulted in Death: Enter date of death and cause of death

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Event Narrative: Provide an account of the event including any information which is not recorded elsewhere on the form.

Research Procedures: Enter details of research procedures (regardless of whether there is a causal relationship with the SAE).
Add the result of unblinding if appropriate

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Primary Source: This is the person who is completing the SAE report. Add contact details. An acknowledgement of receipt will be sent to the Primary Source.

Principal Investigator or designee must confirm that the event is an SAE and sign and date.

Chief Investigator must sign and date if the event is to be reported to the Research Ethics Committee as a **suspected** and **unexpected** SAE.

Fax the completed form to: Pharmacovigilance Office
Fax No: +44(0)141 357 5588

Retain all fax confirmations with the items faxed.

FOLLOW UP REPORTS

If additional information becomes available about an SAE (e.g. a definitive diagnosis or a date of resolution) a follow up report must be submitted to the Pharmacovigilance Office as follows:

- Before any changes are made on the original SAE form, make a copy of the SAE form and retain original form on file.
- On the **copy**, make any changes, additions or updates. All changes must be accurate, legible and verifiable with the source data.
- At the top of the first page indicate that this is a follow-up
- Amend the date of report to the date of the follow-up
- Initial and date all changes.
- Fax the form to the Pharmacovigilance Office Fax No.: **+44(0)141 357 5588**
- Fax in all four pages even if changes were only made to one or two of the pages.
- File the follow up report in the Study Site File
- Retain all fax confirmations with the items faxed.
- For subsequent follow up reports, take the last SAE follow-up form sent, make a copy and then make all changes on the **copy** and follow the process as described above.

DOWNGRADING OF A REPORTED SAE

If, on receipt of additional information about an event, the Investigator determines a previously reported SAE does not meet any seriousness criteria, follow the steps below to downgrade the SAE:

- Complete a follow-up SAE report as described above.
- In the "Event Narrative" section provide an explanation of why the PI has determined that the event is not to be considered serious (e.g. "It was confirmed that the subject was not hospitalised; therefore, this event does not meet any seriousness criteria")
- Changes have to be countersigned by the PI

For any enquiries regarding the completion of the SAE form, contact the Pharmacovigilance Office
Robertson Centre for Biostatistics,
11th Floor Boyd Orr Building
University of Glasgow,
Glasgow G12 8QQ

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Document History

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1.0	Version 1.0 creation	29/11/13
2.0	Removed from SOP 18.008, Guideline 18.008D and added to SOP 55.004	15/07/2016