TRIAL OFFICE USE: | *Received:* *Initial:* | *Checked:* *Initial:*

PARAMEDIC3 Serious Adverse Event Form—Initial

Medication Route in Cardiac Arrest

Participant Trial Number: ☐☐☐ - ☐☐☐☐☐ **SAE reference number** (*for trial office use only):* ☐☐☐☐

Please report immediately on the PARAMEDIC3 trial database or email wctuqa@warwick.ac.uk

1. EVENT TYPE: *(please confirm 'Yes' or 'No' for each category)*

	No	Yes
1. Death	☐	☐
2. Life-threatening	☐	☐
3. Hospitalisation or prolongation of existing hospitalisation	☐	☐
4. Persistent or significant disability/incapacity	☐	☐
5. Congenital anomaly/birth defect	☐	☐
6. Requires medical intervention to prevent one of the above, or it is otherwise medically significant *(please specify below)*	☐	☐

2. EVENT DETAILS:

1. Date event deemed serious: d d – m o n – y y y y

2. Time event deemed serious: *24 hour clock* ☐☐ : ☐☐

3. Date site aware of this event: d d – m o n – y y y y

4. Location of event: On scene ☐

En-route to hospital ☐

In hospital ☐

3. EVENT DETAILS CONTINUED:

5. Details of Event:

Please include all **relevant** details of the event, any tests performed and associated results:

(Please continue on SAE Continuation Form as necessary)

Please add details of any **relevant** medical history, concomitant medication and associated dates of administration:

(Please continue on SAE Continuation Form as necessary)

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4. CAUSALITY:

1. Was the event related to administration of the study procedures?

☐ Definitely ☐ Probably ☐ Possibly ☐ Unlikely ☐ Unrelated

2. Has the participant withdrawn from participation in the intervention due to this SAE: **No** ☐ **Yes** ☐

If unlikely or unrelated to trial intervention it does not need to be reported

5. OUTCOME OF EVENT: *(please select one only)*

1. Resolved—no sequelae ☐ → **Date of resolution:** d d – m o n – y y y y **Time of resolution:** ☐☐ : ☐☐ *24 hour clock*

2. Resolved— with sequelae ☐ → **Details of sequelae:** _____ **Date of resolution:** d d – m o n – y y y y

3. Unresolved ☐ → Please complete the SAE Follow-up Form as appropriate **Time of resolution:** ☐☐ : ☐☐ *24 hour clock*

4. Death ☐

5. Unresolved at time of death/withdrawal ☐ → Please complete Withdrawal Form as appropriate

Clinician assessing causality (print name): _____

(Please note: your name must be on the trial delegation log with responsibility code F)

Signature: _____ **Date signed:** d d – m o n – y y y y

Form completed by (print name): _____

(Please note: your name must be on the trial delegation log with responsibility code G)

Signature: _____ **Date signed:** d d – m o n – y y y y

TRIAL OFFICE USE:

Received:	*Initial:*	*Checked:*	*Initial:*

Completion Guidelines for CRF PARAMEDIC3 Serious Adverse Event Form

Form dates:	Use format: 0 6 - J U N - 1 9 5 6
Date and time deemed Serious	This is the date and time when an adverse event is considered to be serious i.e. date the AE fitted one of the event types in box 1.
Date site became aware of the event	Date the investigator team at site first became aware of this event—this may be different from the date the event was deemed to be serious. **N.B. GCP requires that investigators report all SAEs to the trial sponsor 'immediately' or at least within 24 hours of their first knowledge of the event**

Was the event related to administration of the study procedures?

Unrelated:	There is no evidence of any causal relationship
Unlikely:	There is little evidence to suggest a causal relationship (e.g. because the event did not occur within a reasonable time after administration of the trial treatment). There is another reasonable explanation of the event (e.g. the patient's clinical condition, other concomitant medications).
Possibly:	There is some evidence to suggest a causal relationship (e.g. because the event occurs within a reasonable time after administration of the trial treatment). However, the influence of other factors may have contributed to the event (e.g. the patient's clinical condition, other concomitant medications).
Probably:	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definitely:	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.

If an SAE Continuation Form is required, it must be signed and dated by both the person who has responsibility for completing the SAE Form and the Clinical member of staff responsible for assessing causality; the signatures must appear on your Site Signature and Delegation Log.