



CRF05: Event Form

March 2012 Version 2.0

Please fax [redacted] or email [redacted]
within 24hrs of notification of event

Event affecting patient Event affecting crew

1. Event Details (Complete as applicable):

Date of Event <i>(dd/mm/yyyy)</i>		Device serial No																
Crew IDs/names:		Station Name:						Vehicle Call Sign:										
Date of cardiac arrest: <i>(dd/mm/yyyy)</i>		Case No:						Patient DoB <i>(dd/mm/yyyy)</i>										

2. Description of Event (Please continue on separate sheet as necessary)

3. Follow up Information

Resolved? Y N Date resolved _____

4. Reason for Reporting (all patients in this trial will be in an immediately life threatening situation; death or hospitalisation is certain. The options below should only be ticked if they were clearly caused by the event.)

- Death Y N
- Life-threatening event Y N
- In-patient hospitalisation or prolongation of existing hospitalisation Y N
- Persistent or significant disability/incapacity Y N
- Other medically significant reason for reporting Y N

If other please specify.....

Notified by (signature) _____ Print Name _____

Date of Report dd/mm/yyyy _____

OFFICE USE ONLY

Event No: _____

Was the event an ADE Yes No

Was the event an SADE? Yes No

Was the event an Incident? Yes No

Checked by clinical reviewer: _____

Date of review: _____

Was the event related? Yes No

Was the event unexpected Yes No

Device Failure? Yes No

User error? Yes No