Nottingham University Hospitals NHS
NHS Trust

# Standard Operating Procedure (SOP)

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|---|---|---|
| 1 | Jan 2012 | New SOP |
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## 1. INTRODUCTION

In order to comply with Medical Devices Regulations 2002, ISO/FDIS 14155:2011 and Standards for Good Clinical Practice (GCP), it is important that all researchers are aware of the different definitions related to adverse events in research and how to record, report and review each of these specific occurrences. It is essential that all adverse events which occur during the course of a study are recorded and reported appropriately in order to ensure that patient safety is maintained. Adverse events are reportable from the time of study enrolment. For medical device trials the time of enrollment is defined as the time at which, following recruitment, a subject signs and dates the informed consent form.
Adverse events relating to trials involving medical devices can be classified in to different categories (Further information on these categories is provided in section 4):

- Adverse events (AE)
- Adverse Device Effect (ADE)
- Serious Adverse Device Effect(SADE)
- Serious Adverse Event (SAE)
- Anticipated Serious Adverse Device Effect (ASADE)
- Unanticipated Serious Adverse Device Effect (USADE)

Investigator assessment of causality and expectedness is of particular importance.

## 2. SCOPE

This SOP is applicable to all researchers undertaking projects that fall within Medical Devices Regulations 2002 that are sponsored by Nottingham University Hospitals NHS Trust where the study involves *Non-CE marked devices* or *CE marked devices* that are being used outside the intended use(s) covered by the CE marking.
The principles within this document must be followed, however, if applicable, and only with prior agreement with the sponsor the content may be modified to be study specific and meet the needs of individual studies.
For the purpose of this guidance and based on the definitions in section 4, the following events are considered reportable events:

| |
|---|
| • Any SAE, |
| • Any Investigational Medical Device Deficiency that might have led to a SAE if;<br>a) Suitable action had not been taken or,<br>b) Intervention had not been made or,<br>c) If circumstances had been less fortunate |

## 3. Abbreviations

| | |
|---|---|
| Admin | R&I Administrator |
| AE | Adverse Event |
| ADE | Adverse Device Effect |
| ASADE | Anticipated Serious Adverse Device Effect |
| CI | Chief Investigator |
| CIB | Clinical investigation Brochure |
| CIP | Clinical Investigation Plan |
| NUH | Nottingham University Hospitals NHS Trust |
| MHRA | Medicines and Healthcare Products Regulatory Agency |
| PI | Principal Investigator |
| QA | Quality Assurance |
| R&I | Research and Innovation |
| SAE | Serious Adverse Event |
| SADE | Serious Adverse Device Effect |
| TMF | Trial Master File |
| USADE | Unanticipated Serious Adverse Device Effect |

## 4. Definitions

### 4.1 Medical device

A medical device is any instrument, apparatus, implement, machine, appliance, implant, software, material, or other similar or related article:

a) Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

1) Diagnosis, prevention, monitoring, treatment or alleviation of disease,
2) Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury,
3) Investigation, replacement, modification, or support of the anatomy or of a physiological process,
4) Supporting or sustaining life,
5) Control of conception,
6) Disinfection of medical devices, and

b) Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means

N.B: The term “medical device” is usually defined by national regulations. For the purposes of this International Standard, this definition does not list “in vitro diagnostic medical devices” (see ISO 13485:2003, definition 3.7[1]).

### 4.2 Investigational medical device

An investigational medical device is a medical device being assessed for safety or performance in a clinical investigation. This includes medical devices already on the market that are being evaluated for new intended uses, new populations, new materials or design changes.

### 4.3 Adverse Event (AE)

An adverse event is any untoward medical occurrence, unintended disease or injury or any untoward clinical signs in a subject enrolled in a clinical trial, including occurrences which are not necessarily caused by or related to the medical device/intervention.

An adverse event can therefore be any unfavourable and unintended sign (including abnormal lab results), symptom or disease temporally associated with the use of the medical device/intervention, whether or not considered to be related to the medical device/intervention.

For medical device trials the time of enrolment is defined as the time at which, following recruitment, a subject signs and dates the informed consent form.

### 4.4 Intensity:

The intensity of an adverse event will initially be assessed according to the following definitions:

| Intensity | Description |
|---|---|
| Mild | An event easily tolerated by the patient, causing minimal discomfort and not interfering with everyday activities |
| Moderate | An event sufficiently discomforting to interfere with normal everyday activities |
| Severe | An event that prevents normal everyday activities |

### 4.5 Serious Adverse Event (SAE)

An adverse event is defined by the ISO14155:2011 guidelines for medical device trials as serious if it:

| |
|---|
| a). Results in death or |
| b). Is a life-threatening illness or injury or |
| c). Requires hospitalisation or prolongation of existing hospitalisation or |
| d). Results in persistent or significant disability or incapacity or |
| e) Medical or surgical intervention required to prevent any of the above |
| f). Leads to foetal distress, foetal death or consists of a congenital anomaly or birth defect or |
| g). Is otherwise considered medically significant by the investigator. |

Life threatening in the definition of an SAE refers to an event in which the subject was at risk of death <u>at the time of the event</u>**;** it does not refer to an event that hypothetically might have caused death if it were more severe.
Medical judgement should be exercised in deciding whether an SAE is serious in other situations.

<u>Important:</u> AE's 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 or the other outcomes listed, should be considered serious

A planned hospitalization for a pre-existing condition, or a procedure required by the Clinical Investigation Plan (CIP), without a serious deterioration in health, is not considered to be a serious adverse event.

### 4.6 Adverse Device Effect (ADE)

An ADE is an adverse event related to the use of an investigational medical device. This includes any adverse event resulting from insufficiencies or inadequacies in the instructions for use, the deployment, the implantation, the installation, the operation, or any malfunction of the investigational medical device.

An ADE includes any event that is a result of use error or intentional misuse. Use error refers to an act or omission of an act that results in a different device response than intended by the manufacturer or expected by the user. An unexpected physiological response of the subject does not in itself constitute a use error.

### 4.7 Serious Adverse Device Effect (SADE)

A SADE is an adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event (refer to section 4.5). This includes device deficiencies that might have led to a serious adverse event if:

| |
|---|
| • Suitable action had not been taken or |
| • Intervention had not been made or |
| • If circumstances had been less fortunate |

### 4.8 Anticipated Serious Adverse Device Effect (ASADE)

A serious adverse device effect which by its nature, incidence, severity or outcome has been previously identified in the risk analysis report or Clinical Investigation Brochure.

### 4.9 Unanticipated Serious Adverse Device Effect (USADE)

Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report or Clinical Investigation Brochure.

### 4.10 Adverse event categorisation

| **Adverse events** | **Non-device related** | **Device or procedure related** | |
|---|---|---|---|
| **Non-serious** | **Adverse Event (AE)** | **Adverse Device Effect (ADE)** | |
| **Serious** | **Serious Adverse Event (SAE)** | **Serious Adverse Device Effect (SADE)** | |
| | | **Anticipated** | **Unanticipated** |
| | | **Anticipated Serious Device Effect (ASADE)** | **Unanticipated Serious Device Effect (USADE)** |

### 4.11 Causality

The relationship between the investigational medical device and the occurrence of each adverse event will be assessed and categorised. The investigator will use clinical judgement to determine the relationship. Alternative causes, such as natural history of the underlying diseases, concomitant therapy, other risk factors etc. will be considered. The Investigator will also consult the current version of the risk analysis report and/or investigator brochure where available.

**Causality assessments;**

| Relationship | Description |
|---|---|
| Not related: | No relationship with investigational device. Other factor(s) certainly or probably causative. |
| Related: | Temporal relationship of the onset of the event, relative to use of the device, is reasonable and there is no other cause to explain the event. |

## 5. Responsibilities and Reporting Process

There are a number of responsibilities when managing adverse events. Below is a list of responsibilities for the Investigator and R&I. The responsibilities described follow the life cycle of a study. Please refer to flow diagram (appendix 1).

### 5.1 R&I responsibilities:

5.1.1 As soon as a trial for which R&I is acting on behalf of NUH as Sponsor; receives Notification of Acceptance from the MHRA, the R&I Administrator (or delegated individual) will ensure that the trial is appropriately registered on DOCUMAS. The trial should be flagged on DOCUMAS as 'pending' until Final NHS permission to commence recruitment is granted. Upon issuing the final NHS Permission, the trial status should be changed to 'active'.

5.1.2 Prior to commencing study recruitment investigators and study personnel will receive training relating to their responsibilities for adverse event reporting for NUH sponsored studies as part of the site initiation visit conducted by R&I. For further information please refer to NUH SOP 45 -Site initiation, available on the R&I website http://nuhrise.org/standard-operating-procedures/

5.1.3 The R&I fax machine and the rdsae@nuh.nhs.uk email box will be checked twice daily for any reports received by one of the R&I administration team(Admin) according to a rota set up with agreement of all individuals involved, allowing for absence and leave cover. Upon checking both routes of contact, a rota form will be signed/dated and the time documented. Admin staff will also ensure the fax machine is maintained.

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## 5.2 Investigator responsibilities in the event of an AE/ADE/SAE/ (U)SADE:

### 5.2.1 Recording Adverse Events

For the avoidance of doubt, ALL AE/SAEs should be collected for all trial subjects from the time of their enrolment into the study. For medical device trials the time of enrolment is defined as the time at which, following recruitment, a subject signs and dates the informed consent form.
The Investigator must ensure that the dignity, rights, safety and well being of subjects are given priority at all times and must take appropriate action to ensure the safety of all staff and patients in the study. The Investigator will consider what actions, if any, are required and in what timeframe.
In the event of an adverse event, the investigator (or delegated member of the research team) must review all documentation (e.g., hospital notes, laboratory and diagnostic reports) relevant to the event. The event and relevant comments must then be recorded in the subject's medical notes (or source data where this is not the medical notes).

Except where the protocol states otherwise, all adverse events should be recorded in detail on a case record form or equivalent to allow analysis at a later stage.

### 5.2.2 Investigator review of laboratory reports:

The Investigator will review all laboratory reports and comment on any clinically important out of range values. All clinically important abnormal laboratory tests occurring during the trial will be repeated at appropriate intervals until they either return to baseline or to a level deemed acceptable by the Investigator and the Sponsor (or its designated representative), or until a diagnosis that explains them is made.

***Clinically significant laboratory abnormalities should be reported as adverse events.***

Out of range values that are not clinically significant should be marked 'NCS' on the laboratory report and the report should be signed and dated by the investigator or delegated individual.

### 5.2.3 For all events:

When an AE/ADE occurs in a trial sponsored by NUH the PI, or delegated individual, makes an assessment as to whether it is defined as serious, using the definitions in section 4.0 and in consultation with both the Clinical Investigational Plan (CIP) and Clinical Investigation Brochure (CIB) where available.

### 5.2.4 For non-serious events:

If the event is defined as not serious, it should be recorded in the medical records, or source data, where this is not the medical records ie CRF. Minimal information recorded should include;

- Concomitant medication

- Causal relationship to device as per definitions in section 4.4
- Intensity as per definitions in section 4.3

### 5.2.5 For serious events:

If the event is defined as serious - a SAE or device deficiency that could have led to (U)SADE:

**If a serious event occurs the Investigator must quarantine the device as soon as possible**

Until the MHRA has been given the opportunity to carry out an investigation, the device **should not** be:

- **discarded**
- **repaired**
- **returned to the manufacturer**

All material evidence, i.e. devices/parts removed, replaced or withdrawn from use following an incident, instructions for use, records of use, repair and maintenance records, packaging materials, or other means of batch identification **must** be:

- **clearly identified and labelled**
- **stored securely.**

Evidence should not be interfered with in any way except for safety reasons or to prevent its loss. Where appropriate, a record should be made of all readings, settings and positions of switches, valves, dials, gauges and indicators, together with any photographic evidence and eyewitness reports.

N.B: Consideration should be given to the practicality and implications of quarantining the device; for example if the device is an implantable device all further local supplies of the device should be quarantined as a precaution until further advice is sought.

### 5.2.6 SADE Reporting:

**Investigator responsibilities:**

For ALL serious adverse events related to an investigational medical device the investigator is responsible for notifying:

- **the Sponsor (NUH)**
- **and the Research Ethics Committee (REC)**

### 5.2.7 Reporting to the sponsor:

If the event is classified as an SADE the NUH medical device reporting form for serious adverse device effects.(appendix 2) should be used and is available on the Research and Innovation web site:
http://nuhrise.org/document-libraries/document-library/.

The completed form must be sent to R&I **within 24hrs** of any member of the research team becoming aware of the event either by:

- **email to: rdsae@nuh.nhs.uk**

***or***

- **Fax to: 0115 849 3295**

The Chief Investigator must be copied in on the notification.

**NB: If the PI is unavailable to sign the SADE form the study team should not delay in sending the SADE report to R&I. A copy of the original submitted form signed by the PI must be forwarded to R&I as soon as possible.**

**Investigator & R&I responsibility:**

R&I will acknowledge receipt of the SADE notification by noon of the following working day; either to the fax machine or email address, from which the initial notification was received (appendix 4).
If acknowledgement of the SADE is not received by the person sending the notification within 24 hours, then it is the responsibility of the Investigator (or delegated member of the research team) to contact R&I immediately.

### 5.2.8 Reporting to the regulatory authority:

### R&I responsibilities:

Incidents should be reported to the regulatory authority **as soon as possible,** via the MHRA online reporting system accessed from the *'reporting adverse incidents involving medical devices'* section of the MHRA website available from:
http://aic.mhra.gov.uk/mda%5CMDAFormsV3.nsf/webTForms/DDFD54795BFAB1A080257953004E6150?edit

NUH R&I will inform the device manufacturer of the event. The device should not be returned to the manufacturer until the MHRA have completed their investigation.

NUH R&I will inform the medical device liaison officer at NUH, this is the Head of Clinical Engineering.

If the study is multicentre NUH R&I will inform all Principal Investigators involved in the study about the event.

### 5.2.9 Reporting to the research ethics committee:

### Investigator responsibilities:

If the event is classified as an SAE the investigator must report to the research ethics committee (REC) using the NRES safety reporting form for all studies except clinical trials of investigational products (Appendix 3). Available from:
http://www.nres.npsa.nhs.uk/applications/after-ethical-review/safetyreports/safety-reports-for-all-other-research/

A copy of the completed REC form should be sent to R&I either by:

- **email to: rdsae@nuh.nhs.uk**

***or***

- **Fax to: 0115 849 3295.**

### R&I responsibilities

NUH R&I on behalf of the sponsor will confirm receipt of the event report to the study team (appendix 4),, to either the e-mail account or fax from which the report was received- R&I will review the information provided and record the information on DOCUMAS.
If this confirmation of receipt from R&I is not received to either the e-mail account or fax to which the original report was sent, then the Investigator should contact the R&I office to confirm the receipt of the report.

## 6.0 Follow on Reporting

**Investigator:** After the initial report the investigator is required to actively follow up the subject until either:

a) The SAE/USADE resolves, or
b) Until 30 days after the discontinuation of use of the medical device.

This decision must be documented in the TMF (for NUH sponsored studies) & Site file. Investigators (or delegated persons) will provide follow-up information, each time new information is available.
Where NUH is Sponsor the NUH R&I Research Related SAE/USADE Follow-on Report Form (appendix 5) available on the R&I website http://nuhrise.org/document-libraries/document-library/ will be completed and should be submitted ensuring the report includes the unique reference report allocated by R&I to either the:

- **R&I fax (Fax: 0115 849 3295).**

or

- **email to rdsae@nuh.nhs.uk**

**R&I:** The QA manager, or delegated individual, will liaise with the investigator to gain an update regarding the progress of the SADE/USADE every two weeks until either:.

a) The SADE/USADE resolves, or
b) Until 30 days after the discontinuation of use of the medical device.

### 6.1 Follow on action required from the MHRA investigation.

The investigator and NUH R&I will undertake any requirements outlined in the MHRA investigation and follow up as instructed.

### 6.2 Trust Reportable Incidents

In the same way that adverse incidents, including clinical, non-clinical and near misses can involve patients, staff and visitors during routine care, adverse incidents can also occur during research related activities. An adverse incident can be defined as "an event or circumstance that could have or did lead to unintended or unexpected harm, loss or damage"

It is important that research related adverse incidents are treated in the same way as non-research related adverse incidents. Research related adverse incidents must therefore be reported in accordance with the Trusts own Adverse Incident Reporting Procedures. An example of a research related adverse incident may be lost drugs. This is not an AE but should be reported as an AI.
http://nuhnet/medical_director/integrated_governance/incident_reporting/Pages/report_an_incident.aspx

Events that are both Adverse Incidents and Adverse Events MUST be reported independently following both processes/procedures.

**SOP REVIEW PERIOD**

This procedure will be reviewed by the owner on a biennial basis, unless new local, national and/or international recommendations force an earlier review

**Appendix 1 Flow Diagram**

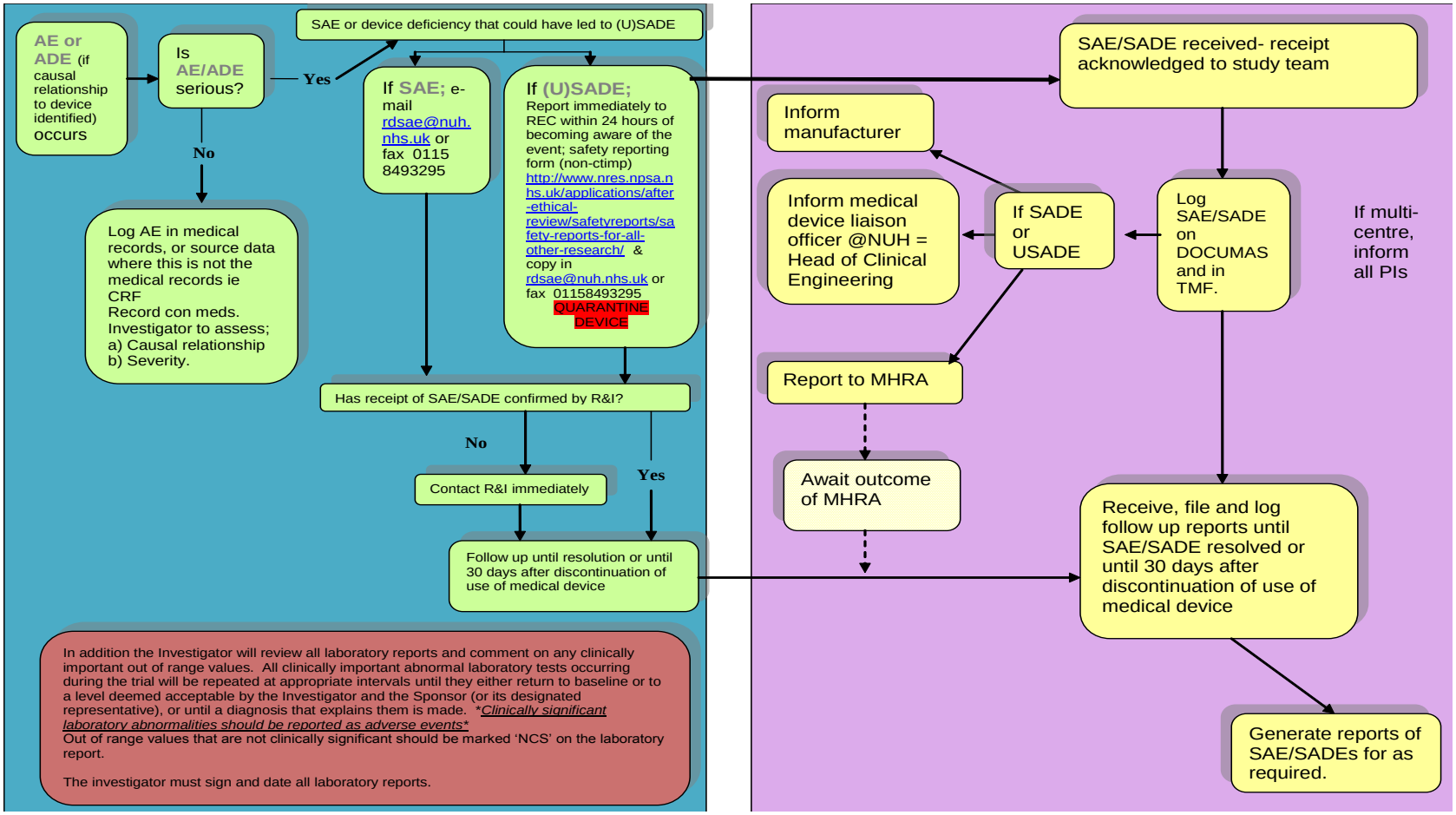
**Appendix 2 NUH Medical Device Reporting Form.Serious Adverse Device Effects**

**Appendix 3 NRES reporting form**

**Appendix 4 NUH Standard e-mail of receipt of report**

**Appendix 5 NUH Medical Device Serious Adverse Device Effects/ (U)SADE Follow-up Form**

Appendix 1


AE or ADE (if causal relationship to device identified) occurs
Is AE/ADE serious?
Yes
No
Log AE in medical records, or source data where this is not the medical records ie CRF
Record con meds.
Investigator to assess;
a) Causal relationship
b) Severity.
SAE or device deficiency that could have led to (U)SADE
If SAE; e-mail rdsae@nuh.nhs.uk or fax 0115 8493295
If (U)SADE;
Report immediately to REC within 24 hours of becoming aware of the event; safety reporting form (non-ctimp) http://www.nres.npsa.nhs.uk/applications/after-ethical-review/safetyreports/safety-reports-for-all-other-research/ & copy in rdsae@nuh.nhs.uk or fax 01158493295
QUARANTINE DEVICE
Has receipt of SAE/SADE confirmed by R&I?
No
Yes
Contact R&I immediately
Follow up until resolution or until 30 days after discontinuation of use of medical device
In addition the Investigator will review all laboratory reports and comment on any clinically important out of range values. All clinically important abnormal laboratory tests occurring during the trial will be repeated at appropriate intervals until they either return to baseline or to a level deemed acceptable by the Investigator and the Sponsor (or its designated representative), or until a diagnosis that explains them is made. *Clinically significant laboratory abnormalities should be reported as adverse events*
Out of range values that are not clinically significant should be marked 'NCS' on the laboratory report.
The investigator must sign and date all laboratory reports.
SAE/SADE received- receipt acknowledged to study team
Inform manufacturer
Inform medical device liaison officer @NUH = Head of Clinical Engineering
If SADE or USADE
Log SAE/SADE on DOCUMAS and in TMF.
If multi-centre, inform all PIs
Report to MHRA
Await outcome of MHRA
Receive, file and log follow up reports until SAE/SADE resolved or until 30 days after discontinuation of use of medical device
Generate reports of SAE/SADEs for as required.

**1. Project Identifiers:**

| Site Number: | Investigator's name: |
|---|---|
| Project Title: | |

**2. Site details:**

| Reported By: | Print name: | |
|---|---|---|
| Contact details: | Tel: | Email: |

**3.. Subject Identifiers:**

| Initials: | Participant ID: | Date of Birth: __ __/__ __ __/__ __ __ __ dd / mmm / yyyy | Sex: Male ☐ Female ☐ |
|---|---|---|---|

**4. Event/Effect Information:**

| Date of Onset: __ __/__ __ __/__ __ __ __ dd / mmm / yyyy |
|---|
| Event / Effect: |
| Description of Event/Effect: *Further information e.g. Lab Tests/Results, Signs & Symptoms related to Diagnosis* |

**5. Action Taken Regarding Study Device:**

| None ☐ Removed/ Discontinued ☐ Other (specify)☐ _____ |
|---|
| Detail treatment given: |

**6. Serious Criteria** *(tick all that apply)*

- Death ☐
- Life threatening illness or injury ☐
- Hospitalisation or prolonged of hospitalisation ☐
- Permanent impairment of body structure or body function ☐
- Medical or surgical intervention required to prevent any of the above ☐
- Led to foetal distress, foetal death or congenital anomaly or birth defect ☐
- Other (maybe protocol specific) ☐ - Specify:_____

**7. Causality:**

| Detail all possible and suspected causes: |
|---|

| |
|---|
| |

**8. Relationship of the Event/Effect to the Device?**

| |
|---|
| Related ☐ Not Related ☐ |

**9. Event/Effect anticipated?**

| |
|---|
| Anticipated ☐ Unanticipated ☐ |

**10. Classification of SAE/SADE:**

| | | |
|---|---|---|
| Device Related | Anticipated Serious Adverse Device Effect - (ASADE) | ☐ |
| | Unanticipated Serious Adverse Device Effect - (USADE) | ☐ |
| Not related to device | Serious Adverse Event – (SAE) | ☐ |

**11. Investigational Medical Device Information –** *Detail all devices:*

| Device | Start date of device utilisation | End Date of device utilisation |
|---|---|---|
| | __ __/__ __ __/__ __ __ __<br>dd / mmm / yyyy | __ __/__ __ __/__ __ __ __<br>dd / mmm / yyyy |
| | __ __/__ __ __/__ __ __ __<br>dd / mmm / yyyy | __ __/__ __ __/__ __ __ __<br>dd / mmm / yyyy |

**12. Event Outcome:**

| | | | |
|---|---|---|---|
| 1) | Recovered: | Yes: ☐ No: ☐ | If yes, date of recovery: __ __/__ __ __/__ __ __ __<br>dd / mmm / yyyy |
| 3) | Ongoing: | Yes: ☐ No: ☐ | If yes, details: |
| 4) | Recovered with sequelae: | Yes: ☐ No: ☐ | If yes, date: __ __/__ __ __/__ __ __ __<br>dd / mmm / yyyy<br>Details: |
| 5) | Subject Died: | Yes: ☐ No: ☐ | If yes, date of death: __ __/__ __ __/__ __ __ __<br>dd / mmm / yyyy |

**13. Principal Investigator**

| | | |
|---|---|---|
| Investigator Signature: | | Date: __ __/__ __ __/__ __ __ __<br>dd / mmm / yyyy |

## REPORTING INSTRUCTIONS

*Send Copy to R&D within 24hrs from becoming aware of the event by either:*

1. Hand-deliver a copy of this form to:
   Research & Innovations
   Nottingham Integrated Clinical Research Centre,
   C floor, South Block,
   Queens Medical Centre Campus,
   Nottingham University Hospitals NHS Trust,
   Nottingham, NG7 2UH

   or
2. email a copy to rdsae@nhs.nuh.uk,

   *or*
3. Fax a copy to: 0115 8493295 and phone Research & Innovations Dept on 0115 9709049 or 0115 9249924 ext 70659 or 70660 to confirm arrival.

   Any queries please contact a member of staff in the Research & Innovations department:
   Telephone: 0115 9709049 or 0115 9249924 ext 70659 or 70660

**Retain this form in the Trial Master File**

**For Internal Use**
**Medical Monitor/Chief Investigator**

| | | |
|---|---|---|
| Medical Monitor or CI: | | |
| Confirm Classification: | Yes ☐ No ☐ ⇨if no state reason and re-classify: | |
| Signature: | | Date: __ __/__ __ __/__ __ __ __<br>dd / mmm / yyyy |

National Patient Safety Agency

National Research Ethics Service

# REPORT OF SERIOUS ADVERSE EVENT (SAE)

**(For all studies except clinical trials of investigational medicinal products)**

The Chief Investigator should report any SAE that is both related to the research procedures and is unexpected. Send the report to the Research Ethics Committee that gave a favourable opinion of the research within 15 days of the CI becoming aware of the event.

## 1. Details of Chief Investigator

| | |
|---|---|
| *Name:* | |
| Address: | |
| Telephone: | |
| Email: | |
| Fax: | |

**2. Details of study**

| | |
|---|---|
| Full title of study: | |
| Name of main REC: | |
| Main REC reference number: | |
| Research sponsor: | |
| Sponsor's reference for this report: (if applicable) | |

## 3. Type of event

*Please categorise this event, ticking all appropriate options:*

| | | |
|---|---|---|
| Death ☐ | Life threatening ☐ | Hospitalisation or prolongation of existing hospitalization ☐ |

| | | |
|---|---|---|
| Persistent or significant disability or incapacity ☐ | Congenital anomaly or birth defect ☐ | Other ☐ |

**4. Circumstances of event**

| | |
|---|---|
| Date of SAE: | |
| Location: | |
| Describe the circumstances of the event:<br><br>*(Attach copy of detailed report if necessary)* | |
| What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed? | |

**5. Declaration**

| | |
|---|---|
| Signature of Chief Investigator: | |
| Print name: | |
| Date of submission: | |

**6. Acknowledgement of receipt by main REC (please insert name):**

The [ ] Research Ethics Committee acknowledges receipt of the above.

| | |
|---|---|
| Signed: | |
| Name: | |
| Position on REC: | |

| | |
|---|---|
| Date: | |

*Signed original to be sent back to Chief Investigator (or other person submitting report)*

*Copy to be kept for information by main REC.*

**NUH R&I sponsor ref:**

**Title:**

**pal Investigator:**

**sor:** **Nottingham University Hospitals NHS Trust**

This e-mail confirms receipt of the above SAE/(U)SADE by this R&I office acting on behalf of NUH as project sponsor. The event has been allocated the reference number of **XXXX,** please quote this reference on communications relating to this event and on all follow on reports.

Kind regards,

Research and Innovation
NICRC C-Floor
Nottingham University Hospitals NHS Trust
Queens Medical Centre Campus
Nottingham
NG7 2UH
Direct Dial: 0115 9249924 ext 70659
Fax: 0115 8493295

For further information about R&D and a comprehensive list of SOPs and processes please visit our new website: the url to www.nuhrise.org

Please consider the environment before printing this e-mail

# FAX NOTICE

**Queens Medical Centre Campus**

Research and Innovation
Nottingham University Hospital NHS Trust
NINRC-C Floor
Derby Road
Nottingham
NG7 2UH

Tel: 0115 924 9924
Fax: 0115 8493295

www.nuh.nhs.uk

Dear xxxxxxxxxxxxxxxxxx,

**NUH R&I sponsor ref:**

**Study Title:**

**Principal Investigator:**

**Sponsor:** **Nottingham University Hospitals NHS Trust**

This fax letter confirms receipt of the above SAE/(U)SADE by this R&I office acting on behalf of NUH as project sponsor. The event has been allocated the reference number of **XXXX**, please quote this reference on communications relating to this event and on all follow on reports.

Kind regards,

Queens Medical Centre Campus
Nottingham
NG7 2UH
Direct Dial: ext 70659
Fax: 0115 8493295

For further information about R&D and a comprehensive list of SOPs and processes please visit our new website: the url to www.nuhrise.org

**1. Project Identifiers:**

| Site Number: | Investigator's name: |
|---|---|
| Project Title: | |

**2. Site details:**

| Reported By: | Print name: | |
|---|---|---|
| Contact details: | Tel: | Email: |

**3. Subject Identifiers:**

| Initials: | Participant ID: | Date of Birth: | Sex: |
|---|---|---|---|
| | | __ __/__ __ __/__ __ __ __<br>dd / mmm / yyyy | Male ☐ Female ☐ |

**4. Additional details of SAE/(U)SADE since initial report:**

*Signs & Symptoms related to Diagnosis, Lab or other test results, relevant to assessment of case:*

**5. Additional Action taken since initial report:**

None ☐ Removed/ Discontinued Device☐ Other (specify)☐ _____

Detail further action/treatment given:

**6. Outcome:**

| | | | |
|---|---|---|---|
| 1) | Recovered: | Yes: ☐ No: ☐ | If yes, date of recovery: __ __/__ __ __/__ __ __ __ dd / mmm / yyyy |
| 3) | Ongoing: | Yes: ☐ No: ☐ | If yes, details: |
| 4) | Recovered with sequelae: | Yes: ☐ No: ☐ | If yes, date: __ __/__ __ __/__ __ __ __ dd / mmm / yyyy<br>Details: |
| 5) | Subject Died: | Yes: ☐ No: ☐ | If yes, date of death: __ __/__ __ __/__ __ __ __ dd / mmm / yyyy<br>Give cause and PM details if available: |
| Did the patient continue on the study as per protocol? Yes: ☐ No: ☐ | | | |
| Was the patient withdrawn from the study? Yes: ☐ No: ☐ | | | |

**7. Concomitant Medication:**

| Concomitant Medication | Dose | Route | Start date of administration | End Date of Administration |
|---|---|---|---|---|
| | | | __ __/__ __ __/__ __ __ __ dd / mmm / yyyy | __ __/__ __ __/__ __ __ __ dd / mmm / yyyy |
| | | | __ __/__ __ __/__ __ __ __ dd / mmm / yyyy | __ __/__ __ __/__ __ __ __ dd / mmm / yyyy |
| | | | __ __/__ __ __/__ __ __ __ dd / mmm / yyyy | __ __/__ __ __/__ __ __ __ dd / mmm / yyyy |
| | | | __ __/__ __ __/__ __ __ __ dd / mmm / yyyy | __ __/__ __ __/__ __ __ __ dd / mmm / yyyy |
| | | | __ __/__ __ __/__ __ __ __ dd / mmm / yyyy | __ __/__ __ __/__ __ __ __ dd / mmm / yyyy |

**8. Principal Investigator:**

| | | |
|---|---|---|
| Name of Principal Investigator at reporting site: | | |
| Signature: | | Date: __ __/__ __ __/__ __ __ __ dd / mmm / yyyy |

*Send Copy to R&I by either:*

1. email a copy to: rdsae@nuh.nhs.uk

*or*

2. Fax a copy to: 0115 8493295 and phone Research & Innovations Dept on 0115 9709049 or 0115 9249924 ext 70659 or 70660 to confirm arrival.

Any queries please contact a member of staff in the Research & Innovations department:
Telephone: 0115 9709049 or 0115 9249924 ext 70659 or 70660

**A copy should also be sent to the Chief Investigator & Retain form in the Investigator Site File**

**For Internal Use**
**Medical Monitor/Chief Investigator**

| | | |
|---|---|---|
| Chief Investigator: | | |
| Comments: | | |
| Signature: | | Date: __ __/__ __ __/__ __ __ __<br>dd / mmm / yyyy |