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- **GENERATE FORM and obtain PI/Sub-I signature.**
- **EMAIL** completed form within **24 HOURS** of knowledge of the event to indreporting@cuanschutz.edu
- Please provide as much information as available.

Serious Adverse Event (SAE) Reporting Form-Medical Device

Protocol Number: _____

Site Name: _____

Subject ID:

_____

Date aware of event (dd-mmm-yyyy):

Type of Report:

☐ Initial ☐ Follow-up ☐ Final

Subject Information

Subject Initials: _____

D.O.B (dd-mmm-yyyy):

Ethnicity: ☐ Hispanic/Latino

☐ Not Hispanic/Latino

Sex: ☐ Male ☐ Female

Weight: _____ ☐ lbs ☐ kg

Race: ☐ American Indian/Alaska Native

☐ Asian

☐ Black or African American

☐ Native Hawaiian/Other Pacific Islander

☐ White

☐ Other, please specify: _____

Investigational Medical Device Information

Protocol Title and Number:

Trade/Brand Name of the device: _____

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Operator of the device: ☐ Health Professional ☐ Patient/Consumer ☐ Other (please specify): _____

Indication for use: _____

Dose, frequency and Route of administration/use (if applicable): _____

Date of first use (dd-mmm-yyyy): _____

Date of Last use (dd-mmm-yyyy): _____

Was the use of investigational device stopped after SAE occurred: ☐ Yes ☐ No

Did the event abate after the investigational device was stopped? (If applicable)
☐ Yes ☐ No ☐ Not Applicable

Did the event reappear after the investigational device was stopped? (If applicable)
☐ Yes ☐ No ☐ Not Applicable

Is the study Blinded? ☐ Yes ☐ No If blinded: ☐ Single Blind ☐ Double Blind

Was the study blind broken? ☐ Yes ☐ No
If yes, please provide treatment assignment: _____

What are you reporting?

☐ SAE only

☐ SAE associated with device malfunction.

☐ Device malfunction only

Note: If you are only reporting device malfunction, please skip over the section for serious adverse event information.

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If there was a device malfunction, please provide the summary of device malfunction below:

Serious Adverse Event Information

Serious Adverse Event Term and Grade: _____

(Multiple events can be captured in single SAE report form if all parameters match e.g., date of first use/date of last use, seriousness criteria, relationship to the investigational device etc.)

Date of Onset (dd-mmm-yyyy):

Frequency of the event: ☐ Once (single episode) ☐ Intermittent ☐ Continuous ☐ Unknown

Is the SAE an exacerbation of the pre-existing condition: ☐ Yes ☐ No

If yes, please specify:

Was the event Unanticipated? ☐ Yes ☐ No

Was the event related to protocol violation? ☐ Yes ☐ No

Was the event related to the research procedure? ☐ Yes ☐ No

Was the event a study related endpoint? ☐ Yes ☐ No

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Did the event resolve? ☐ Yes ☐ No If yes, date resolved (dd-mmm-yyyy): _____
If not, the event should be followed to resolution and reported to the IND/IDE office using this SAE report form.

SAE Criteria (Check all that apply)	**Action taken**	**Event Outcome**
☐ Death ☐ Life-threatening ☐ Hospitalization (Initial or prolonged) ☐ Disability/incapacity ☐ Congenital Anomaly/birth defect ☐ Required intervention to prevent permanent impairment.	☐ No Action ☐ Device schedule adjusted ☐ Dose Interrupted ☐ Dose Increased ☐ Dose Reduced ☐ Temporary discontinuation ☐ Device permanently Removed/Discontinued Date: ☐ ☐ Other (please provide details) ☐	☐ Resolved (recovered) ☐ Resolved with sequelae. If resolved with sequelae, provide information on sequelae. Further assessment from PI is needed if the sequelae is serious. ☐ Ongoing (Not resolved) ☐ Improved (resolving/recovering) ☐ Worsened ☐ Fatal ☐ Unknown

Relationship to the investigational device	**Relationship to the research procedure (if applicable)**
☐ Unrelated ☐ Unlikely Related ☐ Possibly Related ☐ Probably Related ☐ Definite	☐ Unrelated ☐ Unlikely Related ☐ Possibly Related ☐ Probably Related ☐ Definite

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Brief description of the nature of the SAE (attach description if more space is needed):

What steps were taken to treat the SAE?

Relevant tests/laboratory data, including dates:

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Other relevant history, including pre-existing medical conditions (e.g. allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.):

Concomitant medical products and therapy dates:

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Death Information

Did the patient die? ☐ Yes ☐ No

If yes, complete the following:

Cause of death:_____ Date of death (dd-mmm-yyyy): _____

Was a death certificate obtained? ☐ Yes ☐ No ☐ Pending

Was autopsy performed? ☐ Yes ☐ No ☐ Pending
If yes, please attach a copy to this report.

Investigator's Name:_____

Investigator's signature:_____ Date (dd-mmm-yyyy): _____

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Please follow these documentation guidelines to properly document and report a serious adverse event.

1. Please notify the IND/IDE office via email within **24 hours** of occurrence of the serious adverse event (SAE), irrespective of it being related/unrelated to the interventional medical device or anticipated/unanticipated from an IND.

2. An SAE is defined as any adverse experience that results in any of the following outcomes:

A. Led to a death.
- Check if death was an outcome of the adverse event.
- Please note Death is typically not an acceptable event term. Death is an event outcome, and more information and justification will be requested in cases where death is reported as an event term. Every effort should be made to report the cause of death.
- In cases where multiple SAEs were reported for the subject at the time of death, only the single event term should have the event outcome recorded as death. Please record the primary event term that may be closely associated with the subject's death, for which the event outcome will be marked as Death.

B. Life-threatening:
- Check if suspected that the patient was at substantial risk of dying at the time of the adverse event. it does not refer to an event which hypothetically might have caused death if it were more severe.

C. Hospitalization (initial or prolonged):
- Check if admission to the hospital or prolongation of hospitalization was a result of the adverse event.
- Check if the patient was admitted to the hospital for one or more days or even if released on the same day.
- Check in the case where emergency room visit results in admission to the hospital.
- **Do not check if:** the patient in the hospital received a medical product and subsequently developed an otherwise nonserious adverse event **UNLESS** the adverse event prolonged the hospital stay.
  Note: Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious (medically important event).

D. Disability or Permanent Damage:

- Check if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions or caused a permanent impairment of a body structure or a body function.

E. Congenital Anomaly/Birth Defect:

- Check if suspected that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.

F. Other Serious (Important Medical Events):

- Check when, based on appropriate medical judgment, the event may jeopardize the patient and may require medical or surgical intervention to prevent one of the other outcomes listed above.
- Important medical events may not be immediately life-threatening or result in death or hospitalization but may jeopardize the patient or may require intervention to prevent one of the other outcomes listed in the definition above. These should also usually be considered serious.

NOTE: Planned hospitalization for pre-existing condition, or a procedure required by the Clinical Investigation Plan, without a serious deterioration in health, is not considered a serious adverse event

3. An SAE should be followed until it resolves/resolves with sequelae, becomes chronic or is no longer clinically significant. This doesn't apply when the subject has been deceased.

4. Provide as much information as available on the SAE report including the following accurate and complete information:

- **Date aware of event:** Date of awareness is when the sponsor-investigator was first aware of the event. This is crucial for timely regulatory reporting to the FDA based on regulatory timelines.

- **Subject Information Section:**
  - Subject's identification- subject initials
  - Subject's date of birth
  - Subject's age
  - Subject's sex
  - Subject's height and weight
  - Subject's race and ethnicity

- **Investigational Medical Device information**
  - Protocol title and number
  - Trade/Brand Name of the device
  - Procode: The assigned FDA Product Classification Code (procode) can be identified using the Product Classification Database search page at

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http://www.accessdata.fda.gov/scripts/cdrh/ cfdocs/cfPCD/classification.cfm

- Manufacturer Name, City and State
- Model #: The exact model number found on the device label or accompanying packaging.
- Catalog #: The exact number as it appears in the manufacturer's catalog, device labeling, or accompanying packaging.
- Serial #: This number can be found on the device label or accompanying packaging; it is assigned by the manufacturer and should be specific to each device.
- Lot #: This number can be found on the label or packaging material.
- Expiration date: If available; this date can often be found on the device itself or printed on the accompanying packaging.
- Unique Device Identifier (UDI) #: This number can be found on the device, its label, or accompanying packaging. The number is located below the barcode and may contain numbers, letters and special characters such as (), /, $, +, =} etc. The UDI begins with one of the following three elements: (01) + =
- Please record all numbers, letters, parentheses, and symbols included in the UDI #
- Operator of Device
  - Indicate the type of person operating or using the suspect medical device on the patient at the time of the event as follows:
  - Health Professional = physician, nurse, respiratory therapist, etc.
  - Patient/Consumer = person being treated, parent/ spouse/friend of the patient
  - Other = nurse's aide, orderly, etc.
- Is this a Single-use Device that was Reprocessed and Reused on a Patient? - Indicate "Yes" or "No". If yes, Enter Name and Address of Reprocessor. Any entity that reprocesses single-use devices for reuse in humans is the manufacturer of the reprocessed single-use device.
- Indication for use
- Dose, frequency and Route of administration/use: Add if applicable.
- Date of first use
- Date of Last use
- Check whether the investigational device was stopped after the SAE occurred.
- Effect of Dechallenge and Rechallenge should be determined (if applicable): Indicate if the event abated after the investigational device was stopped/explanted and did the event reappear after re-introduction/re-implant of the investigational device.

  Dechallenge = withdrawal of investigational device

  - resolution of suspected event when the investigational device is withdrawn is a strong although not conclusive indication of device induced disease.
  - Positive Dechallenge is a response observed for the reduction or disappearance of adverse reactions (AR) on withdrawal of a device from a patient.

    Rechallenge = reintroducing the investigational device after a dechallenge.
  - This is only justifiable when the benefit of re-introducing the investigational device to the patient outweighs the risk of recurrence of the reaction. This is rare. In some cases, the reaction may be more severe on repeat exposure.

- If Applicable, check whether the study is blinded. If yes, please specify if single or double-blinded and provide the treatment assignment if the blind is broken.

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- **Serious Adverse Event Information section:**

  Adverse Device Effect (ADE): Adverse event related to the use of an investigational medical device.

  NOTE 1- 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.

  NOTE 2- This includes any event that is a result of a use error or intentional abnormal use of the investigational medical device.

  - **Serious Adverse Event Term**: Please record **definitive or provisional diagnosis** instead of sign and symptoms. If diagnosis is uncertain, all signs and symptoms that are serious should be recorded as separate events using this form.

    For Example: Subject reported pain, cold sweat, fatigue, nausea and heartburn and the physician diagnosed the condition to be Myocardial infraction, please capture only the diagnosis as myocardial infraction as an SAE.

    Note: Upon initial assessment within 24 hours if a diagnosis may not be clear, signs and symptoms may be recorded. Every effort should be made to update the event term once a diagnosis is known.

  - Event terms should be concise, using a medical diagnosis when known. The **underlying etiology of the event should not be combined with the event term**. If both the underlying etiology of the event and the event term are serious, please report them separately.**For example**: Subject developed anemia secondary to acute hemorrhage and needed emergency intervention, in this case both anemia and acute hemorrhage should be captured as two separate SAEs.
  - In case of occurrence **of multiple SAEs for a subject capture all SAEs in a single SAE report form if all parameters for the event terms match** (i.e., start date, stop date, intensity, relationship etc.).
  - Please provide the severity grade for the SAE based on the grading scale used in the study protocol.
  - Onset date of the event
  - Check whether the frequency of the event was once, intermittent, continuous or unknown.
  - Check whether the SAE was an exacerbation of a pre-existing condition. If yes, specify the condition.
  - Provide information on whether the event was Unanticipated. Unanticipated adverse device effect means any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.
  - Check if the event was related to protocol violation or research procedure.
  - **Check the appropriate SAE criteria** - check all that apply for the SAE.
  - **Relationship to Study intervention**-To be determined by the Investigator.

Definitely Related: the serious event is associated with the investigational device or with procedures beyond reasonable doubt when:

- the event is a known side effect of the product category the device belongs to or of similar devices and procedures.
- the event has a temporal relationship with investigational device use/application or procedures.
- the event involves a body-site or organ: that of the investigational device or procedures are applied to/the investigational device or procedures have an effect on.
- the serious event follows a known response pattern to the medical device (if the response pattern is previously known).
- the discontinuation of medical device application (or reduction of the level of activation/exposure) and reintroduction of its use (or increase of the level of activation/exposure), impact on the serious event (when clinically feasible).
- other possible causes (e.g., an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment) have been adequately ruled out.
- harm to the subject is due to error in use.
- the event depends on a false result given by the investigational device used for diagnosis, when applicable.
- In order to establish the relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious event.

Probable: the relationship with the use of the investigational device seems relevant and/or the event cannot reasonably explained by another cause, but additional information may be obtained.

Possible: the relationship with the use of the investigational device is weak but cannot be ruled out completely. Alternative causes are also possible (e.g. an underlying or concurrent illness/ clinical condition or/and an effect of another device, drug or treatment). Cases were relatedness cannot be assessed or no information has been obtained should also be classified as possible.

Unlikely: the relationship with the use of the device seems not relevant and/or the event can be reasonably explained by another cause, but additional information may be obtained.

Unrelated: relationship to the device or procedures can be excluded when: - the event is not a known side effect of the product category the device belongs to or of similar devices and procedures.

- The event has no temporal relationship with the use of the investigational device or the procedures.

- the serious event does not follow a known response pattern to the medical device (if the response pattern is previously known) and is biologically implausible.
- the discontinuation of medical device application or the reduction of the level of activation/exposure - when clinically feasible - and reintroduction of its use (or increase of the level of activation/exposure), do not impact on the serious event.
- The event involves a body-site or an organ not expected to be affected by the device or procedure.
- The serious event can be attributed to another cause (e.g. an underlying or concurrent illness/ clinical condition, an effect of another device, drug treatment or other risk factors).
- The event does not depend on a false result given by the investigational device used for diagnosis, when applicable.
- harms to the subject are not clearly due to use error.
- In order to establish the non-relatedness, not all the criteria listed above might be met at the same time, depending on the type of device/procedures and the serious event.

- **Action taken:** Check what action was taken with the investigational device.

- **Event outcome** - if the event is ongoing, the event should be followed to resolution and reported in this form as a follow-up. If the event is considered resolved with sequelae, please provide the description of the sequelae. Sequelae should be captured as an adverse event.

  - **Fatal**: the event is the cause of patient's death or one of the causes of patient's death.
  - **Not resolved**: the event is ongoing; no improvement is observed.
  - **Resolved**: the event is fully resolved or stabilized; return to baseline condition for chronic disorders.
  - **Resolved with sequelae**: the event is resolved, but patient has some permanent condition as a consequence of the event (e.g., mild paranesthesia following transient ischemic attack).
  - **Resolving**: the event is improving, lab results returned improved results, patient's general condition is better but not fully resolved/stabilized or returned to baseline condition.
  - **Worsening** refers to an increase in the severity of a disease or its signs and symptoms.
  - **Unknown**: There is no information on the event's outcome.

- **Description of the SAE**: Provide, in as much detail as possible, a description of the SAE. A typed summary is acceptable, and description may be attached, if needed. Describe the event in detail including a description of what happened and a

summary of all relevant clinical information (medical status prior to the event; signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). If available and if relevant, include synopsis of any office visit notes or the hospital discharge summary.
Attach copies of these records with any confidential information deleted. **DO NOT** identify any personal identifiable information (PII) or proprietary information.

- **Steps taken to treat the SAE:** Specify the steps that were taken to treat the SAE.

- **Medical History Section:**
  Please specify subject's pre-existing medical conditions, drug allergies, any alcohol and smoking use. A typed summary is acceptable, and description may be attached, if needed.

- **Laboratory and/or Diagnostic Testing section:**
  Provide all the appropriate laboratory and/or diagnostic tests that are associated. with the event along with their dates.

- **Concomitant Medications Section:**
  List all concomitant medications that were taken within one month of the subject enrollment (or as specified in the protocol) including those used to treat the SAE. Include medication name, indication, dose, route, frequency, date medication started, and date medication stopped.

- **Death information:**

- Indicate if the subject died - if yes, complete this section.
- Cause and date of death- cause of death should be determined by the investigator.
- Chek if the death certificate was obtained or pending and if autopsy was performed.