SERIOUS ADVERSE EVENT (SAE) FORM FOR

Clinical Investigation of a Medical Device (CIMD)

|  |
| --- |
| **GUIDANCE FOR THE PERSON COMPLETING THIS FORM** |
| 1. Forms must be submitted to ACCORD **within 24 hours** of the site research team becoming aware of the SAE. 2. **Do not include** personal identifiers (patient names, initials, dates of birth, CHI numbers, etc) on this form. 3. Do not include any supplementary information or documents unless requested by ACCORD. 4. Complete the form as far as possible. The form can be updated/signed and re-submitted as new information becomes available. 5. Any updates should be added to the original form – **DO NOT**create a new form for each update to this SAE. 6. Forms must be submitted via email in a PDF format to [**safety@accord.scot**](mailto:safety@accord.scot) |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **1. REPORT DETAILS** | | | | | |
|  |  |  |  |  |  |
| **Trial Name:** |  |  | **Date of Report:** |  |  |
|  |  |  |  |  |  |
| **Sponsor Number:** | **AC** |  | **Centre ID:** |  |  |
|  |  |  |  |  |  |
| **Participant ID:** |  |  | **Centre Name:** |  |  |
|  |  |  |  |  |  |
| **Date PI informed of SAE:** |  |  | **Centre Country:** |  |  |
|  |  |  |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **2. EVENT DETAILS** | | | | | |
|  |  |  |  |  |  |
| **Date of Occurence:** |  |  | **Diagnosis\*:** |  |  |
| **\*The Diagnosis is the Main Event (or symptom) for which the seriousness criteria(s) apply. There should be ONE Main Event per form. If there are two events, please complete two forms** | | | | | |
|  | | | | | |
| **Description**  **of SAE:**  *(1000 character limit)*  **If any event/symptom mentioned in the Description of SAE area meets a seriousness criteria in their own right, a separate SAE form will need to be completed** |  | | | |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Seriousness Criteria:**  *(Tick all that apply)* |  | Death | |  | Foetal distress, foetal death, Congenital Abnormality, Birth Defect |
|  | Permanent impairment of a body structure or a body function including chronic diseases | |  | Medical or surgical intervention to prevent life-threatening illness or injury, or a permanent impairment to a body structure or body function |
|  | Life-threatening illness or injury | |  | Inpatient hospitalisation or prolongation  of existing inpatient hospitalisation |
|  | Other significant medical event | |  |  |
| **Other SAE Criteria:**  *(To be ticked IF other criteria(s) apply, left blank if not)* | Recommendation of the DMC | | |  | New events/reactions likely to affect the safety of participants |
| Post Trial USADE | | |  | Device deficiency that might have led to a serious adverse device effect if:  a) Suitable action had not been taken or  b) Intervention had not been made or  c) If circumstances had been less fortunate |
| **Severity of Event:** | Mild  Moderate  Severe | | | | |
| **Is the SAE a result of a device deficiency?** | Yes  No | | ***If yes, ACCORD CR012-T02 Medical Device Deficiency Form must also be completed*** | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **3. INVESTIGATIONAL DEVICE** | | | | | | | | | | | |
| **Did participant receive trial procedure/intervention prior to SAE?** | | | Yes | | | No *if no, please proceed to section 4* | | | | | |
| **Name of device** | | **Indication for use** | **Route of Administration or fitting** | | **Start Date or first use** | | **End Date**  *Tick box if ongoing* | | **Is SAE causally related to device?** | | |
| **1** |  |  |  | |  | |  |  | Unrelated |  | Possibly Related |
| **2** |  |  |  | |  | |  |  | Unrelated |  | Possibly Related |
| **3** |  |  |  | |  | |  |  | Unrelated |  | Possibly Related |
| **Rationale for causality assessment:**  **The causality assessment (and expectedness if required) has to be made using the event / symptom mentioned in the Diagnosis box** | |  | | | | | | | | | |
| **The section below must only be completed when the SAE is POSSIBLY RELATED to the Device** | | | | | | | | | | | |
| **Expectedness:** | | Anticipated | | *the event is consistent with the Risk analysis/Investigator Brochure* | | | | | | | |
| Unanticipated | | *the event is non consistent with Risk analysis/Investigator Brochure* | | | | | | | |
| **Document name, version number and date used to assess expectedness:** | |  | | | | | | | | | |
|  | | | | | | | | | |
| **Rationale for expectedness assessment:** | |  | | | | | | | | | |
| **Device Name:** | |  | | | | | | | | | |
| **Model Number:** | |  | | | | | | | | | |
| **Serial number:** | |  | | | | | | | | | |
| **Lot/batch number:** | |  | | | | | | | | | |
| **Software version (if applicable):** | |  | | | | | | | | | |
| **Accessories/associated devices affected:** | |  | | | | | | | | | |
| **Name of product owner/manufacturer:** | |  | | | | | | | | | |
| **Has the device been quarantined?** | | Yes  No  If no, provide rationale: | | | | | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **4. OUTCOME OF EVENT** | | | |
| **Any follow-up information relevant to this section can be added to existing (e.g. initial) information.**  **DO NOT cross through or otherwise obscure existing information, and do not use a new form for follow-up reports.** | | | |
| **Outcome of Event** | **Additional Information** | | **Initials and Date** |
| *\*\* Ongoing outcomes: \*\** | | | |
| **Condition still present and unchanged** |  | |  |
| **Condition deteriorated** |  | |  |
| **Condition Improving** |  | |  |
| *\*\* Final outcomes: \*\** | | | |
| **Completely Recovered** | **Date Recovered:** | |  |
| **Recovered with sequelae** | **Date Recovered:** | |  |
| **Death** | **Date of Death:**  **Post mortem:**  Yes  No |  |  |

|  |
| --- |
| **5. ADDITIONAL INFORMATION** (e.g. relevant medical history, concomitant medications, laboratory tests) |
|  |

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **6. INFORMATION SOURCE FOR INITIAL REPORT** | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| **Name / job title of person completing report:** | | / | | | | | | | | | |  |
|  | | | | | | | | | | | | |
| **Email:** |  | | | | | | **Telephone:** | |  | | |  |
|  | | | | | | | | | | | | |
| **PI Name** |  | | **PI Signature:** | | *Date:* | | | | | | |  |
|  | | | | | | | | | | | | |
| **ALL Reports must be signed and dated by the Principal Investigator** *(or suitably qualified clinician listed on the delegation log)*  If signatory is unavailable, the unsigned form must still be sent within 24 h reporting period | | | | | | | | | | | | |
| **7. INFORMATION SOURCE FOR FOLLOW-UP no. 1** | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| **Name / job title of person completing report:** | | / | | | | | | | | | |  |
|  | | | | | | | | | | | | |
| **Email:** |  | | | | | | | **Telephone:** | |  |  | |
|  | | | | | | | | | | | | |
| **PI Name** |  | | | **PI Signature:** | | *Date:* | | | | |  | |
|  | | | | | | | | | | | | |
| **ALL Reports must be signed and dated by the Principal Investigator** *(or suitably qualified clinician listed on the delegation log)*  If signatory is unavailable, the unsigned form must still be sent within 24 h reporting period | | | | | | | | | | | | |
| **8. INFORMATION SOURCE FOR FOLLOW-UP no. 2** | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| **Name / job title of person completing report:** | | / | | | | | | | | | |  |
|  | | | | | | | | | | | | |
| **Email:** |  | | | | | | | **Telephone:** | |  |  | |
|  | | | | | | | | | | | | |
| **PI Name** |  | | | **PI Signature:** | | *Date:* | | | | |  | |
|  | | | | | | | | | | | | |
| **ALL Reports must be signed and dated by the Principal Investigator** *(or suitably qualified clinician listed on the delegation log)*  If signatory is unavailable, the unsigned form must still be sent within 24 h reporting period | | | | | | | | | | | | |
| **Original wet signature forms must be filed in the Investigator Site File (ISF).**  **ACCORD will retain a copy on file.** | | | | | | | | | | | | |