SERIOUS ADVERSE EVENT (SAE) FORM

Non-CTIMP

|  |
| --- |
| **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:** |  |  | **Centre ID:** |  |  |
|  |  |  |  |  |  |
| **Participant ID:** |  |  | **Centre Name:** |  |  |
|  |  |  |  |  |  |
| **Date PI informed of SAE:** |  |  | **Centre Country:** |  |  |
|  |  |  |  |  |  |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **2. EVENT DETAILS** | | | | | |
|  |  |  |  |  |  |
| **Date of Onset:** |  |  | **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)* |  | Congenital anomaly/birth defect | |  | Inpatient hospitalisation or prolongation  of existing inpatient hospitalisation |
|  | Involved persistent or significant disability or incapacity | |  | Life-threatening |
|  | Other significant medical event | |  | Participant died |
| **Severity of Event:** | Mild  Moderate  Severe | | | | |
| **Is the event due to progression of underlying disease?** | Yes  No | | | | |
| **What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed?** | | |  | | |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **3. STUDY INTERVENTION** | | | | | | | | | | |
| **Participant’s treatment allocation if not blinded (assume intervention if blinded)** | | | Control/Standard Care | | | Intervention | | | | |
| **Did participant receive the intervention prior to SAE?** | | | Yes | | | No  *if no, please section proceed to section 4* | | | | |
| **Intervention / Study Procedure** | | | **Start Date** | | **End Date**  *Tick box if ongoing* | | | **Is SAE causally related to intervention?** | | |
| **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 study intervention / procedure** | | | | | | | | | | |
| **Expectedness:** | | Expected | | *The type of event is expected in line with the study intervention* | | | | | | |
| Unexpected | | *The type of event was not listed in the protocol or related documents/literature as an expected occurrence* | | | | | | |
| **Rationale for expectedness assessment:** | |  | | | | | | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **4. OUTCOME OF SAE** | | | |
| **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 SAE** | **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 (for any additional follow-ups please use form CR006-T04)** | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| **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.** | | | | | | | | | | | | |