**MEDICAL DEVICE DEFICIENCY FORM**

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| **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 device deficiency. **Device deficiency should be submitted to ACCORD within 7 days of being made aware of the Device Deficiency for Device Deficiency that are not linked to a potential SAE and within 24h for Device deficiency linked to a potential 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. 6. Forms must be submitted via email in a PDF format to [**safety@accord.scot**](mailto:safety@accord.scot) |

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| **1. REPORT DETAILS** | | | | | |
|  |  |  |  |  |  |
| **Trial Name:** |  |  | **Date of Report:** |  |  |
|  |  |  |  |  |  |
| **Sponsor Number:** | AC |  | **Centre ID:** |  |  |
|  |  |  |  |  |  |
| **Participant ID:** |  |  | **Centre Name:** |  |  |
|  |  |  |  |  |  |
| **Date PI informed of Device Deficiency:** |  |  | **Centre Country:** |  |  |
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| **2. EVENT DETAILS** | | | |
| **Date of deficiency:** |  | | |
| **Is this a deficiency with respect to:** | Identity  Quality  Durability  Reliability  Safety  Performance  Usability | | |
| **Is the device deficiency due to:** | Malfunction  Error  Inadequate labelling | | |
| **Please provide further details:** |  | | |
| **Did the Device Deficiency caused a Serious Adverse Event:** | | Yes  No | **If one of the responses is YES, please report this on the Serious Adverse Event Form for CIMDs (CR012-T01)** |
| **Could the Device Deficiency 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** | | Yes  No |

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| **3. DEVICE DETAILS** | |
| **Device Name:** |  |
| **Model Number:** |  |
| **Serial number:** |  |
| **Lot/batch number:** |  |
| **Software version (if applicable):** |  |
| **Accessories/associated devices affected:** |  |
| **Name of product owner/manufacturer:** |  |
| **Describe the nature of the device, its normal (label) applications and its application in the Clinical Investigation affected if different:** |  |

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| **4. ACTION TAKEN** | |
| **No action taken** | **Device discontinued due to deficiency** |

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| **5. ADDITIONAL INFORMATION** |
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| **6. INFORMATION SOURCE FOR INITIAL REPORT** | | | | | | | | | | | | |
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| **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 the 7 days or 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 the 7 days or 24 h reporting period | | | | | | | | | | | | |
| **8. INFORMATION SOURCE FOR FOLLOW-UP no. 2** | | | | | | | | | | | | |
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| **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 the 7 days or 24 h reporting period | | | | | | | | | | | | |
| **Original wet signature forms must be filed in the Investigator Site File (ISF).**  **ACCORD will retain a copy on file.** | | | | | | | | | | | | |