

**Report Supplementary Material 18 Serious Adverse Event Form**

**UK FROST: Serious Adverse Event Form**

Brief study title: **United Kingdom Frozen Shoulder Trial (UK FROST)**

Participant ID number:

Today's Date:  /  /

Participant's DoB:   /   /

Male  Female

Location and description of event:

Start date:   /   /

Stop date:   /   /

Duration if less than 24 hours (hrs:mins)   :

**Classification of Serious Adverse Event (please cross all boxes that apply):**

- |  |  |   |
|--|--|---|
| <input type="checkbox"/> Death   | <input type="checkbox"/> Prolonged hospitalisation | <input type="checkbox"/> Life threatening                 |
| <input type="checkbox"/> Persistent or significant disability/incapacity | <input type="checkbox"/> Required hospitalisation  | <input type="checkbox"/> Congenital anomaly/ birth defect |
| <input type="checkbox"/> Other medically important condition             |  |   |

**Please state outcome of event at time of this report**

Resolved  Ongoing

Date resolved   /   /

Resolved with sequelae (specify below & give date):-  Ongoing with sequelae (specify below):-

Date:   /   /

Died Date of death   /   /

Cause of death

- Action taken:**
- |   |  |
|---|--|
| <input type="checkbox"/> None   | <input type="checkbox"/> Therapy prescribed/ other likely action |
| <input type="checkbox"/> Study treatment interrupted/halted                                 | <input type="checkbox"/> Discontinued treatment                  |
| <input type="checkbox"/> Other (please specify): <input style="width: 350px;" type="text"/> |  |

**Relationship of event to any of the research procedures (to be completed by PI or delegated Clinician)**

Not related  Unlikely to be related  Possibly related  Probably related  Definitely related

**Is this event expected? (to be completed by PI or delegated Clinician)**  Yes  No

Researcher's name <input style="width: 240px;" type="text"/>	Researcher's signature <input style="width: 210px;" type="text"/>	Date <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
Local PI's name <input style="width: 240px;" type="text"/>	Local PI's signature <input style="width: 210px;" type="text"/>	Date <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
CI name <input style="width: 240px;" type="text"/>	CI signature <input style="width: 210px;" type="text"/>	Date <input type="text"/> / <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

**Please fax this form to York Trials Unit on 01904 321387 within 24 hours of becoming aware of the event.**