Report Supplementary Material 17 Adverse Event Form

UK FROST: Adverse Event Form

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

Principal Investigator: _____ **Hospital name:** _____

Participant ID number: ☐☐☐☐ **Participant's DoB:** ☐☐ / ☐☐ / ☐☐☐☐

Description of event (medical terminology):

Start date: ☐☐ / ☐☐ / ☐☐☐☐ **Stop date:** ☐☐ / ☐☐ / ☐☐☐☐

Duration if less than 24 hours (hrs:mins) ☐☐ : ☐☐ **Grading of event:** ☐ Mild ☐ Moderate ☐ Severe

Outcome:

☐ Resolved ☐ Ongoing

Date resolved ☐☐ / ☐☐ / ☐☐☐☐

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

Date: ☐☐ / ☐☐ / ☐☐☐☐

Action taken:

☐ None ☐ Therapy prescribed/ other likely action

☐ Study treatment interrupted/halted ☐ Discontinued study

☐ Other (please specify): _____

Causality: (relationship to study treatment)	Not related	Unlikely to be related	Possibly related	Probably related	Definitely related
	☐	☐	☐	☐	☐

Expectedness of event: ☐ Expected ☐ Unexpected (i.e. not described in the protocol or other safety information for study treatment)

Seriousness: Is this event considered to be a serious adverse event (SAE)? ☐ Yes* ☐ No

Fax a copy of this form to the York Trials Unit on 01904 321387 within 5 days of becoming aware of the event

*If considered SERIOUS please complete a **UK FROST Trial Serious Adverse Event (SAE) form**. Please fax it **AND** this form (if completed) to the **York Trials Unit on 01904 321387** within 24 hours of becoming aware of the event.

Signature: _____ Print name: _____

(To be completed by PI or delegated Clinician)

Date: ☐☐ / ☐☐ / ☐☐☐☐