IRAS no. 307628

Early **R**ib **A**nalgesia with **SER**ratus: **ERASER** Trial

A Pragmatic Randomised Control Trial Evaluating the Clinical and Cost-Effectiveness of Serratus Anterior Plane Block with Catheter Insertion compared to Usual Care in Patients with Multiple Rib Fractures

CHANGE OF STATUS FORM

This trial uses eCRF only and all data should be entered onto **https://bctu-redcap.bham.ac.uk**. This form illustrates the data that is being collected when the participant is partially or fully withdrawn from trial activities, died before reaching the end of the follow up period or is lost to follow up.

Section 1 - PARTICIPANT'S DETAILS

Trial no: ☐☐☐☐☐ | Partial date of birth: *e.g. Jan2017* M M M Y Y Y Y | Site ID: ☐☐☐☐☐

Section 2 - LEVEL OF PARTICIPATION

Partial withdrawal: stop participating in certain trial activity. **Full withdrawal:** stop participating in ALL trial activities including death.

The participant has: *Select one*

◯ Partially withdrawn *(go to section 3)* ◯ Fully withdrawn/deceased *(go to section 4)* ◯ Failed Intervention *(go to section 5)*

◯ Did not receive randomised treatment (go to section 6) ◯ Lost to follow up *(go to section 7)*

Section 3 - PARTIAL WITHDRAWAL

Partial withdrawal requested by: *Select one*

◯ Participant ◯ Consultee/legal representative ◯ Researcher ◯ Other person --➤

Please specify: _____

Date researcher notified: *e.g. 31Jan2017* D D M M M Y Y Y Y

Please select the change in level of participation:

☐ **No trial intervention**: no longer wishes to receive the trial intervention, but is willing to be followed up in accordance with the schedule of assessments and using any central UK NHS bodies for long term outcome

☐ **No trial related follow up:** no longer wishes to attend trial visits but is willing to be followed up at standard clinic visits and using any central UK NHS bodies for long term outcomes.

Main reason for stopping *Select one.*

◯ Participant felt the assessments take too much time ◯ Participant not comfortable answering some of the questionnaires

◯ Participant no longer interested in research ◯ Participant changed mind about treatment ◯ Participant had other commitment

◯ Participant declined to give a reason ◯ Participant relocated to out of area ◯ Unable to tolerate side effects

◯ Had a serious adverse event * ◯ Other, please specify below

Please specify: _____

*** Please make sure the relevant details are provided in the SAE form if it is a SAE that requires reporting as per protocol.**

Skip to section 8

Section 4 - FULL WITHDRAWAL or DECEASED

Participant has: ◯ Deceased ◯ Fully withdrawn

If Deceased

Date of death: *e.g. 31Jan2017* D D M M M Y Y Y Y

Time of death: *24hr clock* H H M M

Cause of death *(as appear on the death certificate)*	**1a**	**1b**	**1c**

If Withdrawn

Partial withdrawal requested by: *Select one*
◯ Participant ◯ Consultee/legal representative ◯ Researcher ◯ Other person ----➤

Please specifiy:

Date researcher notified *e.g. 31Jan2017* D D M M M Y Y Y Y

Main reason for stopping *Select one.*
◯ Participant felt the assessments take too much time ◯ Participant not comfortable answering some of the questionnaires
◯ Participant no longer interested in research ◯ Participant changed mind about treatment ◯ Participant had other commitment
◯ Participant declined to give a reason ◯ Participant relocated to out of area ◯ Unable to tolerate side effects
◯ Had a serious adverse event * ◯ Other, please specify below

Please specify:

*** Please make sure the relevant details are provided in the SAE form if it is a SAE that requires reporting as per protocol.**

Skip to section 8

Section 5 - FAILURE OF INTERVENTION

Reason for failure of intervention:
◯ Unable to insert SAP ◯ Removed within 24 hours ◯ Other (please describe) ----➤

Please Describe:

Skip to section 8

Section 6 - DID NOT RECIEVE RANDOMISED TREATMENT

Which arm was the participant randomised to: ◯ Usual care only ◯ SAP block

Please outline why the participant did not receive the treatment to which they were randomised :

Skip to section 8

Section 7 - LOST TO FOLLOW UP

Please outline how the patient is lost to follow up: *e.g. patient is uncontactable by phone after multiple attempts*

Skip to section 8

Section 8 - COMPLETED BY

This form must be signed by a researcher who has been delegated the duty of data collection on the Site Signature and Delegation Log.

Form completed by: *Full name*	Signature:	Date form completed: *e.g. 31Jan2017* D D M M M Y Y Y Y