



Change of circumstance form

Please complete this form if there are any changes in the circumstance(s) of the SSHew participant

Centre number: [][]

Participant's trial ID number: [][][][][][]

Please enter the date of the change of circumstance: [][] / [][] / 2 0 [][]
Day Month Year

Reason for change in circumstance:

Please read the following and place a cross in the most appropriate box.

1) Participant is withdrawing from the intervention (i.e. no longer wants shoes/ to wear shoes) []

Please state reason if given:

[]

2) Participant no longer wishes to receive:

a) Text messages [] b) CRFs [] c) Follow up phone calls []

(If all three boxes are crossed, this indicates full withdrawal - see next question)

3) Participant is withdrawing fully from the study (i.e. no further follow up) []

Please state reason if given:

[]

4) Participant has died (please also complete a 'Serious Adverse Event Form'). []

Date of death: [][] / [][] / 2 0 [][]
Day Month Year

5) Participant is lost to follow up []

Researcher's Name: []

Researcher's Signature: []

Please enter the date you are completing this questionnaire:

[][] / [][] / 2 0 [][]
Day Month Year

Please fax this form to the York Trials Unit []