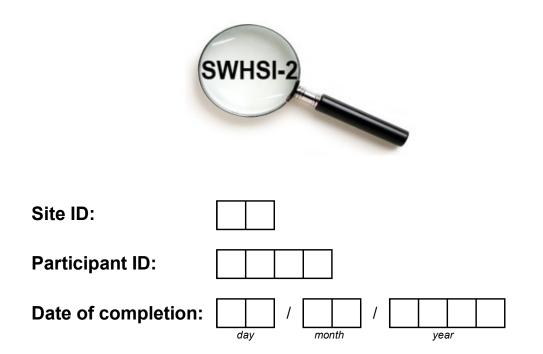


The Department of Health Sciences



SWHSI-2 Trial

Post Healing Assessment Case Report Form



Instructions for Completion

This CRF may be completed by the principal investigator or a delegated member of staff listed on the SWHSI-2 Trial Delegation Log. The first section of this Case Report Form (CRF) should be completed by the participant.

Please refer to the associated SWHSI-2 Trial Specific Procedure for full details of how to complete this CRF.

Please complete all sections of this questionnaire using the spaces provided, and sign off when each visit is complete.

Please do not include any patient identifiable information when completing this CRF. When complete, please remove the staple and take a photocopy of the completed CRF for your site records. **Please do not re-staple the original.** Place the unstapled original in a "SWHSI-2 Trial business reply envelope" and send via post to York Trials Unit.

This project is funded by the National Institute for Health Research Health Technology Assessment Programme (Project number 17/42/94)

Participant ID:						
<u>Section A – Healing Visit 1</u>	<u>Date:</u>	day /	month	/	year]

Please hand the booklet to the participant and ask them to complete the Wound Healing Questionnaire

Not

Α

Quite

Α

1)	Wound Healing Questionnaire	
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		at all	little	a bit	lot
1.	Was there redness spreading away from the wound? (erythema/cellulitis)				
2.	Was the area around the wound warmer than the surrounding skin?	· 🗌			
3.	Has any part of the wound leaked clear fluid? (serous exudate)				
4.	Has any part of the wound leaked blood-stained fluid? (haemoserous exudate)				
5.	Has any part of the wound leaked thick and yellow/green fluid? (pus/purulent exudate)				
6.	Has the area around the wound become swollen?				
7.	Has the wound been smelly?				
8.	Has the wound been painful to touch?				
9.	Have you had, or felt like you have had, a raised temperature or fever? (fever >38°)				
			Yes	No	
10.	Have you sought advice because of a problem with your wound, oth than at a planned follow-up appointment?	ner			
11.	Have you been back into hospital for treatment of a problem with yo wound?	our			
12.	Have you been given antibiotics for a problem with your wound?				
13.	Has your wound been scraped or cut to remove any unwanted tissu (debridement of wound)	e?			
14.	Has your wound been drained? (drained of pus / abscess)				
15.	Have you had an operation under general anaesthetic for treatment a problem with your wound?	of			

Bluebell Wound Healing Questionnaire $\textcircled{}{}^{\odot}$ University of Bristol 2017 Modified with permission.

	Participant ID:
	Please return the booklet to the research nurse.
2)	Has the participant experienced any difficulties completing the Wound Healing Questionnaire?
	If 'Yes', please provide reasons:
	Questions were difficult to understand If 'Yes', please provide the associated question numbers:
	Participant was unable to recall events
	Answer options were insufficient
	Some questions did not apply If 'Yes', please provide the associated question numbers:
	Other, please specify:
3)	CDC assessment
	Has the participant experienced any wound infections during the trial? Yes No
	If 'Yes', how many infections has the participant experienced?
	Start date of first infection:
	Which of the following features were present (please cross all that applied):
	Abscess or other evidence of infection detected on gross anatomical or hisopathologic exam or imaging test
	Aspirated fluid/swab of surgical site yields organisms and pus cells are present
	Clinician's diagnosis
	Fever (temperature 38°C or more)
	Incision spontaneously dehisced or was opened by healthcare professional
	Localised swelling
	Purulent drainage
	Redness
	If the participant has had more than 1 infection, please complete a SWHSI-2 Infection CDC
	Assessment supplementary page.
4)	Healing Status
a)	Can healing of the reference SWHSI be confirmed? Yes No*
	If 'Yes', please provide the date of wound healing, as confirmed by a healthcare professional:
	Please then complete Questions b and c, and arrange healing visit 2.
	*If 'No', please complete this visit section and revert to weekly assessments until the wound is healed.
b)	Has a photograph of the reference SWHSI been obtained? Yes No
	If 'No', please provide reasons why a photograph has not been taken:
c)	Visit Completed by:
	Name: Signature:
	Date: / / / /
	daymonthyearSWHSI-2Post Healing AssessmentCRFPage 3 of 4v 1.103.02.20REC Reference: 19/YH/0054Sponsor Reference: R23193299063990IRAS Reference: 2588023299063990

Γ	Participant ID:
	Section B – Healing Visit 2 Date: day / month / year
1)	Can healing of the reference SWHSI still be confirmed? Yes No* If 'Yes', please then complete Question 2, and arrange healing visit 3. *If 'No', please revert to weekly assessments until the wound is healed.
2)	Visit Completed by: Name: Signature: Date:/
Sec	ction C – Healing Visit 3 Date: day month year
1)	Can healing of the reference SWHSI still be confirmed? Yes No* If 'Yes', please then complete Question 2. *If 'No', please revert to weekly assessments until the wound is healed.
2)	Visit Completed by: Name: Signature: Date: Image: I