

SWHSI-2 Trial

Post Healing Assessment Case Report Form



Site ID:

Participant ID:

Date of completion:

 / /
day month year

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:

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:

Yes No

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: / / Date is: Exact Approximate
day month year

Which of the following features were present (*please cross all that applied*):

Abscess or other evidence of infection detected on gross anatomical or histopathologic 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)

Heat

Incision spontaneously dehiscenced or was opened by healthcare professional

Localised pain and tenderness

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:

/ /
day month year

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: / /
day month year

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: / /
day month year

Section 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: / /
day month year