SWHSI-2 Trial

Weekly Assessments - Monthly Case Report Form

Site ID: ☐☐

Participant ID: ☐☐☐☐

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

Instructions for Completion

*An entry should be made in this CRF for every **completed** visit.*

This CRF may be completed by the principal investigator or a delegated member of staff listed on the SWHSI-2 Trial Delegation Log. There are sufficient spaces to record four participant assessments.

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 CRF using the spaces provided, and sign off when 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.*

Participant ID: ☐☐☐☐ **Visit Date:** ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

Section A – Clinical Events

Please review any previous assessments and AE/SAE forms for ongoing events before completing this section.

Have any of the following events occurred since the last assessment?

Section A1 – Wound Healing

Event	Yes	No	Event Date *(dd/mm/yyyy)*
1) Has healing of the reference SWHSI (confirmed by a healthcare professional) occurred since the last visit?	☐	☐	☐☐ / ☐☐ / ☐☐☐☐
a) If 'No', does the participant think their wound has healed?	☐	☐	

Section A2 – Clinical Events

Event	Yes	No	Event Date *(dd/mm/yyyy)*
1) Did the participant have an infected SWHSI at the last assessment?	☐	☐	
a) If 'Yes', has the infection resolved?	☐	☐	Date of Infection Resolution: ☐☐ / ☐☐ / ☐☐☐☐
2) Has the participant had a new SWHSI infection since their last assessment?	☐	☐	Date of New Infection: ☐☐ / ☐☐ / ☐☐☐☐
If 'Yes'...			
a) Has a SWHSI-2 Trial Adverse Event form been completed?	☐	☐	Adverse Event Number ☐☐
b) Has the new infection been resolved?	☐	☐	Date of Infection Resolution: ☐☐ / ☐☐ / ☐☐☐☐
3) Was the patient an inpatient in relation to their SWHSI or SWHSI treatment at the last assessment	☐	☐	
a) If 'Yes', has the participant been discharged?	☐	☐	Date of Discharge: ☐☐ / ☐☐ / ☐☐☐☐
4) Has the participant been admitted as an inpatient in relation to their SWHSI or SWHSI treatment since the last assessment?	☐	☐	Date of Admission: ☐☐ / ☐☐ / ☐☐☐☐
If 'Yes'...			
a) Has a SWHSI-2 Trial Adverse Event form been completed?	☐	☐	Adverse Event Number ☐☐
b) Has the participant been discharged?	☐	☐	Date of Discharge: ☐☐ / ☐☐ / ☐☐☐☐

5) Return to theatre due to SWHSI ☐ Yes ☐ No ☐☐ / ☐☐ / ☐☐☐☐
dd *mm* *yyyy*

a) If 'Yes', in theatre was the participant's SWHSI *(cross all that apply)*:

☐ Surgically closed (flap) ☐ Surgically closed (skin graft)
☐ Surgically closed (delayed primary healing) ☐ Debrided ☐ Revascularised
☐ Incised and drained ☐ Examined under anaesthetic ☐ Amputated
☐ Angioplasty ☐ Other (please specify)

b) If 'Yes', has a SWHSI-2 Trial Adverse Event form been completed? ☐ Yes ☐ No Adverse Event Number ☐☐

c) Where the participant's SWHSI was closed, was the decision for closure made by a clinician blind to treatment allocation? ☐ Yes ☐ No

d) If 'No', please indicate why this assessment was not blinded:

Please proceed to Section B

Section B – Treatment Status (Visit 1 only)

1. Where is the participant currently receiving treatment? *(cross all that apply)*

☐ Community Clinic ☐ Nursing Home ☐ Patient's home ☐ General ward ☐ ICU

☐ High Dependency Unit ☐ Other (please specify): _____

2. Has the participant's treatment location changed **since the last assessment**? ☐ Yes ☐ No

a) If 'Yes', please select where the treatment was being received previously *(cross all that apply):*

☐ Community Clinic ☐ Nursing Home ☐ Patient's home ☐ General ward ☐ ICU

☐ High Dependency Unit ☐ Other (please specify): _____

3. Please indicate the number of dressing changes the participant has received **since the last assessment** *(select one option)*:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ Other (please specify): ☐☐

4. Please indicate the participants current treatment status *(select one option)*:

a) ☐ Patient continues to receive NPWT with no changes **since the last assessment**
If 'Yes', proceed to Section E

b) ☐ Patient continues to receive Usual Care with no changes **since the last assessment**
If 'Yes', proceed to Section E

c) ☐ Patient continues to receive NPWT but changes have been made **since the last assessment**
If 'Yes', proceed to Question 5

d) ☐ Patient continues to receive Usual Care but changes have been made **since the last assessment**
If 'Yes', proceed to Question 5

e) ☐ Patient has changed from NPWT to Usual Care **since the last assessment**
If 'Yes', proceed to Question 5

f) ☐ Patient has changed from Usual Care to NPWT **since the last assessment**
If 'Yes', proceed to Question 5

5. Please indicate why the patient has had changes made since the last assessment *(cross all that apply)*:

☐ Wound improving ☐ Wound healed ☐ Wound bed prepared

☐ Wound too dry ☐ Deterioration of wound ☐ Failure to maintain seal

☐ Treatment caused pain ☐ No change to wound

☐ Other (please specify): _____

Was the change at: ☐ Patient request ☐ Clinician request

If participant is receiving NPWT, proceed to Section C

If participant is receiving Usual Care, proceed to Section D

Section C – Changes to NPWT Treatment Please only complete if you have selected 4c or 4f

Please provide date change made: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

Please provide details of the NPWT treatment the patient is now receiving *(select one option)*:

1. ☐ V.A.C Ulta (KCI)
☐ V.A.C Via (KCI)
☐ InfoV.A.C (KCI)
☐ ActiV.A.C (KCI)
☐ Renasys (Smith and Nephew)
☐ PICO (Smith and Nephew)
☐ Avance (Molnlycke Health Care)
☐ Avance Solo (Molnlycke Health Care)
☐ Avelle (Convatec)
☐ Other (please specify model and brand):

2. Amount of pressure being used: ☐☐☐ *mmHg*

3. Is the pressure being applied: ☐ Continuously ☐ Intermittently

4. Type of NPWT dressing being used:
☐ Black, polyurethane foam dressings with reticulated (open) pores
☐ White, polyvinyl alcohol with high tensile strength, pre-moistened with sterile water
☐ Antimicrobial gauze (impregnated with Polyhexamethylene biguanide)

5. Has a liner been used with the dressing? ☐ Yes ☐ No

a) If 'Yes', was the liner silver impregnated? ☐ Yes ☐ No

Please proceed to Section E

Section D – Changes to Usual Care Treatment Please only complete if you have selected 4d or 4e

Please provide date change made: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

Please provide details of the Usual Care treatment the patient is now receiving *(cross all that apply)*:

☐ Alginate
☐ Basic wound contact
☐ Cavity Foam
☐ Foam
☐ Gauze Ribbon
☐ Hydrocolloid
☐ Hydrogel
☐ Hydrofoam/Spun Hydrocolloid
☐ Honey
☐ Iodine Containing
☐ PHMB
☐ Protease Modulating matrix
☐ Silver containing
☐ Flamazine silver sulfadiazine dressing
☐ Urgotol silver sulfadiazine dressing
☐ Soft polymer
☐ Superabsorbent
☐ Vapour permeable film or membrane
☐ Other (please specify):
☐ Other (please specify):

Please proceed to Section E

Section E – Other Treatments

1. Is the participant currently using antibiotics? ☐ Yes ☐ No

a) If 'Yes', please indicate the route of administration:

☐ IV ☐ Oral ☐ Other (please specify): _____

b) If 'Yes', please indicate the reason:

☐ Related to SWHSI ☐ Other (please specify): _____

2. Is the participant receiving any other treatment for their SWHSI? ☐ Yes ☐ No

a) If 'Yes', please provide details below *(cross all that apply)*:

☐ Wound Management Systems ☐ Emollient ☐ Silver Nitrate Stick

☐ Dietetic Input ☐ Larvae

☐ Other (please specify): _____

☐ Other (please specify): _____

☐ Other (please specify): _____

Please proceed to Section F

Section F – Visit Checklist and Sign Off

1. All Sections of the Weekly Assessment are complete? ☐ Yes ☐ No

2. Has the next weekly assessment (or first post wound healing visit if wound has healed) been arranged? ☐ Yes ☐ No

Form Completed by (to be completed by delegated clinician or nurse who has reviewed CRF content for this visit)

*Name: _____

Signature: _____

Assessor ID: | |

Date: | | / | | / | | | | |
day *month* *year*

*Must be reflected in the Delegation of Duties Log

Section A – Clinical Events

Please review any previous assessments and AE/SAE forms for ongoing events before completing this section.

Have any of the following events occurred since the last assessment?

Section A1 – Wound Healing

Event	Yes	No	Event Date *(dd/mm/yyyy)*
1) Has healing of the reference SWHSI (confirmed by a healthcare professional) occurred since the last visit?	☐	☐	☐☐ / ☐☐ / ☐☐☐☐
a) If 'No', does the participant think their wound has healed?	☐	☐	

Section A2 – Clinical Events

Event	Yes	No	Event Date *(dd/mm/yyyy)*
1) Did the participant have an infected SWHSI at the last assessment?	☐	☐	
a) If 'Yes', has the infection resolved?	☐	☐	Date of Infection Resolution: ☐☐ / ☐☐ / ☐☐☐☐
2) Has the participant had a new SWHSI infection since their last assessment?	☐	☐	Date of New Infection: ☐☐ / ☐☐ / ☐☐☐☐
If 'Yes'...			
a) Has a SWHSI-2 Trial Adverse Event form been completed?	☐	☐	Adverse Event Number ☐☐
b) Has the new infection been resolved?	☐	☐	Date of Infection Resolution: ☐☐ / ☐☐ / ☐☐☐☐
3) Was the patient an inpatient in relation to their SWHSI or SWHSI treatment at the last assessment	☐	☐	
a) If 'Yes', has the participant been discharged?	☐	☐	Date of Discharge: ☐☐ / ☐☐ / ☐☐☐☐
4) Has the participant been admitted as an inpatient in relation to their SWHSI or SWHSI treatment since the last assessment?	☐	☐	Date of Admission: ☐☐ / ☐☐ / ☐☐☐☐
If 'Yes'...			
a) Has a SWHSI-2 Trial Adverse Event form been completed?	☐	☐	Adverse Event Number ☐☐
b) Has the participant been discharged?	☐	☐	Date of Discharge: ☐☐ / ☐☐ / ☐☐☐☐

5) Return to theatre due to SWHSI ☐ Yes ☐ No ☐☐ / ☐☐ / ☐☐☐☐
dd *mm* *yyyy*

a) If 'Yes', in theatre was the participant's SWHSI *(cross all that apply)*:

☐ Surgically closed (flap) ☐ Surgically closed (skin graft)
☐ Surgically closed (delayed primary healing) ☐ Debrided ☐ Revascularised
☐ Incised and drained ☐ Examined under anaesthetic ☐ Amputated
☐ Angioplasty ☐ Other (please specify)

b) If 'Yes', has a SWHSI-2 Trial Adverse Event form been completed? ☐ Yes ☐ No Adverse Event Number ☐☐

c) Where the participant's SWHSI was closed, was the decision for closure made by a clinician blind to treatment allocation? ☐ Yes ☐ No

d) If 'No', please indicate why this assessment was not blinded:

Please proceed to Section B

Section B – Treatment Status (Visits 2-4 only)

1. Has the location of the patient's treatment changed **since the last assessment**? ☐ Yes ☐ No

a) If 'Yes', please select where the patient is currently receiving treatment *(cross all that apply)*:

☐ Community Clinic ☐ Nursing Home ☐ Patient's home

☐ General ward ☐ ICU ☐ High Dependency Unit

☐ Other (please specify): _____

2. Please indicate the number of dressing changes the participant has received **since the last assessment** *(select one option)*:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ Other (please specify): ☐☐

3. Please indicate the participants current treatment status *(select one option)*:

☐ Patient continues to receive NPWT with no changes **since the last assessment**
If 'Yes', proceed to Section E

☐ Patient continues to receive Usual Care with no changes **since the last assessment**
If 'Yes', proceed to Section E

☐ Patient continues to receive NPWT but changes have been made **since the last assessment**
If 'Yes', proceed to Question 4

☐ Patient continues to receive Usual Care but changes have been made **since the last assessment**
If 'Yes', proceed to Question 4

☐ Patient has changed from NPWT to Usual Care **since the last assessment**
If 'Yes', proceed to Question 4

☐ Patient has changed from Usual Care to NPWT **since the last assessment**
If 'Yes', proceed to Question 4

4. Please indicate why the patient has had changes made since the last assessment *(cross all that apply)*:

☐ Wound improving ☐ Wound healed ☐ Wound bed prepared

☐ Wound too dry ☐ Deterioration of wound ☐ Failure to maintain seal

☐ Treatment caused pain ☐ No change to wound

☐ Other (please specify): _____

Was the change at: ☐ Patient request ☐ Clinician request

If participant is receiving NPWT, proceed to Section C

If participant is receiving Usual Care, proceed to Section D

Section C – Changes to NPWT Treatment Please only complete if you have selected 3c or 3f

Please provide date change made: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

Please provide details of the NPWT treatment the patient is now receiving *(select one option)*:

1. ☐ V.A.C Ulta (KCl)
☐ V.A.C Via (KCl)
☐ InfoV.A.C (KCl)
☐ ActiV.A.C (KCl)
☐ Renasys (Smith and Nephew)
☐ PICO (Smith and Nephew)
☐ Avance (Molnlycke Health Care)
☐ Avance Solo (Molnlycke Health Care)
☐ Avelle (Convatec)
☐ Other (please specify model and brand):

2. Amount of pressure being used: ☐☐☐ *mmHg*

3. Is the pressure being applied: ☐ Continuously ☐ Intermittently

4. Type of NPWT dressing being used:
☐ Black, polyurethane foam dressings with reticulated (open) pores
☐ White, polyvinyl alcohol with high tensile strength, pre-moistened with sterile water
☐ Antimicrobial gauze (impregnated with Polyhexamethylene biguanide)

5. Has a liner been used with the dressing? ☐ Yes ☐ No

a) If 'Yes', was the liner silver impregnated? ☐ Yes ☐ No

Please proceed to Section E

Section D – Changes to Usual Care Treatment Please only complete if you have selected 3d or 3e

Please provide date change made: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

Please provide details of the Usual Care treatment the patient is now receiving *(cross all that apply)*:

☐ Alginate
☐ Basic wound contact
☐ Cavity Foam
☐ Foam
☐ Gauze Ribbon
☐ Hydrocolloid
☐ Hydrogel
☐ Hydrofoam/Spun Hydrocolloid
☐ Honey
☐ Iodine Containing
☐ PHMB
☐ Protease Modulating matrix
☐ Silver containing
☐ Flamazine silver sulfadiazine dressing
☐ Urgotol silver sulfadiazine dressing
☐ Soft polymer
☐ Superabsorbent
☐ Vapour permeable film or membrane
☐ Other (please specify):
☐ Other (please specify):

Please proceed to Section E

Section E – Other Treatments

1. Is the participant currently using antibiotics? ☐ Yes ☐ No

a) If 'Yes', please indicate the route of administration:

☐ IV ☐ Oral ☐ Other (please specify): _____

b) If 'Yes', please indicate the reason:

☐ Related to SWHSI ☐ Other (please specify): _____

2. Is the participant receiving any other treatment for their SWHSI? ☐ Yes ☐ No

a) If 'Yes', please provide details below *(cross all that apply)*:

☐ Wound Management Systems ☐ Emollient ☐ Silver Nitrate Stick

☐ Dietetic Input ☐ Larvae

☐ Other (please specify): _____

☐ Other (please specify): _____

☐ Other (please specify): _____

Please proceed to Section F

Section F – Visit Checklist and Sign Off

1. All Sections of the Weekly Assessment are complete? ☐ Yes ☐ No

2. Has the next weekly assessment (or first post wound healing visit if wound has healed) been arranged? ☐ Yes ☐ No

Form Completed by (to be completed by delegated clinician or nurse who has reviewed CRF content for this visit)

*Name: _____

Signature: _____

Assessor ID: ☐☐

Date: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

*Must be reflected in the Delegation of Duties Log

Participant ID: ☐☐☐☐ **Visit Date:** ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

Section A – Clinical Events

Please review any previous assessments and AE/SAE forms for ongoing events before completing this section.

Have any of the following events occurred since the last assessment?

Section A1 – Wound Healing

Event	Yes	No	Event Date *(dd/mm/yyyy)*
1) Has healing of the reference SWHSI (confirmed by a healthcare professional) occurred since the last visit?	☐	☐	☐☐ / ☐☐ / ☐☐☐☐
a) If 'No', does the participant think their wound has healed?	☐	☐	

Section A2 – Clinical Events

Event	Yes	No	Event Date *(dd/mm/yyyy)*
1) Did the participant have an infected SWHSI at the last assessment?	☐	☐	
a) If 'Yes', has the infection resolved?	☐	☐	Date of Infection Resolution: ☐☐ / ☐☐ / ☐☐☐☐
2) Has the participant had a new SWHSI infection since their last assessment?	☐	☐	Date of New Infection: ☐☐ / ☐☐ / ☐☐☐☐
If 'Yes'...			
a) Has a SWHSI-2 Trial Adverse Event form been completed?	☐	☐	Adverse Event Number ☐☐
b) Has the new infection been resolved?	☐	☐	Date of Infection Resolution: ☐☐ / ☐☐ / ☐☐☐☐
3) Was the patient an inpatient in relation to their SWHSI or SWHSI treatment at the last assessment	☐	☐	
a) If 'Yes', has the participant been discharged?	☐	☐	Date of Discharge: ☐☐ / ☐☐ / ☐☐☐☐
4) Has the participant been admitted as an inpatient in relation to their SWHSI or SWHSI treatment since the last assessment?	☐	☐	Date of Admission: ☐☐ / ☐☐ / ☐☐☐☐
If 'Yes'...			
a) Has a SWHSI-2 Trial Adverse Event form been completed?	☐	☐	Adverse Event Number ☐☐
b) Has the participant been discharged?	☐	☐	Date of Discharge: ☐☐ / ☐☐ / ☐☐☐☐

5) Return to theatre due to SWHSI ☐ Yes ☐ No ☐☐ / ☐☐ / ☐☐☐☐
dd *mm* *yyyy*

a) If 'Yes', in theatre was the participant's SWHSI *(cross all that apply)*:

☐ Surgically closed (flap) ☐ Surgically closed (skin graft)
☐ Surgically closed (delayed primary healing) ☐ Debrided ☐ Revascularised
☐ Incised and drained ☐ Examined under anaesthetic ☐ Amputated
☐ Angioplasty ☐ Other (please specify) _____

b) If 'Yes', has a SWHSI-2 Trial Adverse Event form been completed? ☐ Yes ☐ No Adverse Event Number ☐☐

c) Where the participant's SWHSI was closed, was the decision for closure made by a clinician blind to treatment allocation? ☐ Yes ☐ No

d) If 'No', please indicate why this assessment was not blinded: _____

Please proceed to Section B

Section B – Treatment Status (Visits 2-4 only)

1. Has the location of the patient's treatment changed **since the last assessment**? ☐ Yes ☐ No

a) If 'Yes', please select where the patient is currently receiving treatment *(cross all that apply)*:

☐ Community Clinic ☐ Nursing Home ☐ Patient's home

☐ General ward ☐ ICU ☐ High Dependency Unit

☐ Other (please specify): _____

2. Please indicate the number of dressing changes the participant has received **since the last assessment** *(select one option)*:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ Other (please specify): ☐☐

3. Please indicate the participants current treatment status *(select one option)*:

☐ Patient continues to receive NPWT with no changes **since the last assessment**
If 'Yes', proceed to Section E

☐ Patient continues to receive Usual Care with no changes **since the last assessment**
If 'Yes', proceed to Section E

☐ Patient continues to receive NPWT but changes have been made **since the last assessment**
If 'Yes', proceed to Question 4

☐ Patient continues to receive Usual Care but changes have been made **since the last assessment**
If 'Yes', proceed to Question 4

☐ Patient has changed from NPWT to Usual Care **since the last assessment**
If 'Yes', proceed to Question 4

☐ Patient has changed from Usual Care to NPWT **since the last assessment**
If 'Yes', proceed to Question 4

4. Please indicate why the patient has had changes made since the last assessment *(cross all that apply)*:

☐ Wound improving ☐ Wound healed ☐ Wound bed prepared

☐ Wound too dry ☐ Deterioration of wound ☐ Failure to maintain seal

☐ Treatment caused pain ☐ No change to wound

☐ Other (please specify): _____

Was the change at: ☐ Patient request ☐ Clinician request

If participant is receiving NPWT, proceed to Section C

If participant is receiving Usual Care, proceed to Section D

Section C – Changes to NPWT Treatment Please only complete if you have selected 3c or 3f

Please provide date change made: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

Please provide details of the NPWT treatment the patient is now receiving *(select one option)*:

1. ☐ V.A.C Ulta (KCl)
☐ V.A.C Via (KCl)
☐ InfoV.A.C (KCl)
☐ ActiV.A.C (KCl)
☐ Renasys (Smith and Nephew)
☐ PICO (Smith and Nephew)
☐ Avance (Molnlycke Health Care)
☐ Avance Solo (Molnlycke Health Care)
☐ Avelle (Convatec)
☐ Other (please specify model and brand):

2. Amount of pressure being used: ☐☐☐ *mmHg*

3. Is the pressure being applied: ☐ Continuously ☐ Intermittently

4. Type of NPWT dressing being used:
☐ Black, polyurethane foam dressings with reticulated (open) pores
☐ White, polyvinyl alcohol with high tensile strength, pre-moistened with sterile water
☐ Antimicrobial gauze (impregnated with Polyhexamethylene biguanide)

5. Has a liner been used with the dressing? ☐ Yes ☐ No

a) If 'Yes', was the liner silver impregnated? ☐ Yes ☐ No

Please proceed to Section E

Section D – Changes to Usual Care Treatment Please only complete if you have selected 3d or 3e

Please provide date change made: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

Please provide details of the Usual Care treatment the patient is now receiving *(cross all that apply)*:

☐ Alginate
☐ Basic wound contact
☐ Cavity Foam
☐ Foam
☐ Gauze Ribbon
☐ Hydrocolloid
☐ Hydrogel
☐ Hydrofoam/Spun Hydrocolloid
☐ Honey
☐ Iodine Containing
☐ PHMB
☐ Protease Modulating matrix
☐ Silver containing
☐ Flamazine silver sulfadiazine dressing
☐ Urgotol silver sulfadiazine dressing
☐ Soft polymer
☐ Superabsorbent
☐ Vapour permeable film or membrane
☐ Other (please specify):
☐ Other (please specify):

Please proceed to Section E

Section E – Other Treatments

1. Is the participant currently using antibiotics? ☐ Yes ☐ No

a) If 'Yes', please indicate the route of administration:

☐ IV ☐ Oral ☐ Other (please specify): _____

b) If 'Yes', please indicate the reason:

☐ Related to SWHSI ☐ Other (please specify): _____

2. Is the participant receiving any other treatment for their SWHSI? ☐ Yes ☐ No

a) If 'Yes', please provide details below *(cross all that apply)*:

☐ Wound Management Systems ☐ Emollient ☐ Silver Nitrate Stick

☐ Dietetic Input ☐ Larvae

☐ Other (please specify): _____

☐ Other (please specify): _____

☐ Other (please specify): _____

Please proceed to Section F

Section F – Visit Checklist and Sign Off

1. All Sections of the Weekly Assessment are complete? ☐ Yes ☐ No

2. Has the next weekly assessment (or first post wound healing visit if wound has healed) been arranged? ☐ Yes ☐ No

Form Completed by (to be completed by delegated clinician or nurse who has reviewed CRF content for this visit)

*Name: _____

Signature: _____

Assessor ID: ☐☐

Date: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

*Must be reflected in the Delegation of Duties Log

Section A – Clinical Events

Please review any previous assessments and AE/SAE forms for ongoing events before completing this section.

Have any of the following events occurred since the last assessment?

Section A1 – Wound Healing

Event	Yes	No	Event Date *(dd/mm/yyyy)*
1) Has healing of the reference SWHSI (confirmed by a healthcare professional) occurred since the last visit?	☐	☐	☐☐ / ☐☐ / ☐☐☐☐
a) If 'No', does the participant think their wound has healed?	☐	☐	

Section A2 – Clinical Events

Event	Yes	No	Event Date *(dd/mm/yyyy)*
1) Did the participant have an infected SWHSI at the last assessment?	☐	☐	
a) If 'Yes', has the infection resolved?	☐	☐	Date of Infection Resolution: ☐☐ / ☐☐ / ☐☐☐☐
2) Has the participant had a new SWHSI infection since their last assessment?	☐	☐	Date of New Infection: ☐☐ / ☐☐ / ☐☐☐☐
If 'Yes'...			
a) Has a SWHSI-2 Trial Adverse Event form been completed?	☐	☐	Adverse Event Number ☐☐
b) Has the new infection been resolved?	☐	☐	Date of Infection Resolution: ☐☐ / ☐☐ / ☐☐☐☐
3) Was the patient an inpatient in relation to their SWHSI or SWHSI treatment at the last assessment	☐	☐	
a) If 'Yes', has the participant been discharged?	☐	☐	Date of Discharge: ☐☐ / ☐☐ / ☐☐☐☐
4) Has the participant been admitted as an inpatient in relation to their SWHSI or SWHSI treatment since the last assessment?	☐	☐	Date of Admission: ☐☐ / ☐☐ / ☐☐☐☐
If 'Yes'...			
a) Has a SWHSI-2 Trial Adverse Event form been completed?	☐	☐	Adverse Event Number ☐☐
b) Has the participant been discharged?	☐	☐	Date of Discharge: ☐☐ / ☐☐ / ☐☐☐☐

5) Return to theatre due to SWHSI ☐ Yes ☐ No ☐☐ / ☐☐ / ☐☐☐☐
dd *mm* *yyyy*

a) If 'Yes', in theatre was the participant's SWHSI *(cross all that apply)*:

☐ Surgically closed (flap) ☐ Surgically closed (skin graft)
☐ Surgically closed (delayed primary healing) ☐ Debrided ☐ Revascularised
☐ Incised and drained ☐ Examined under anaesthetic ☐ Amputated
☐ Angioplasty ☐ Other (please specify) _____

b) If 'Yes', has a SWHSI-2 Trial Adverse Event form been completed? ☐ Yes ☐ No Adverse Event Number ☐☐

c) Where the participant's SWHSI was closed, was the decision for closure made by a clinician blind to treatment allocation? ☐ Yes ☐ No

d) If 'No', please indicate why this assessment was not blinded: _____

Please proceed to Section B

Section B – Treatment Status (Visits 2-4 only)

1. Has the location of the patient's treatment changed s**ince the last assessment**? ☐ Yes ☐ No

a) If 'Yes', please select where the patient is currently receiving treatment *(cross all that apply)*:

☐ Community Clinic ☐ Nursing Home ☐ Patient's home

☐ General ward ☐ ICU ☐ High Dependency Unit

☐ Other (please specify): _____

2. Please indicate the number of dressing changes the participant has received **since the last assessment** *(select one option)*:

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

☐ 11 ☐ 12 ☐ 13 ☐ 14 ☐ Other (please specify): | |

3. Please indicate the participants current treatment status *(select one option)*:

☐ Patient continues to receive NPWT with no changes **since the last assessment**
If 'Yes', proceed to Section E

☐ Patient continues to receive Usual Care with no changes **since the last assessment**
If 'Yes', proceed to Section E

☐ Patient continues to receive NPWT but changes have been made **since the last assessment**
If 'Yes', proceed to Question 4

☐ Patient continues to receive Usual Care but changes have been made **since the last assessment**
If 'Yes', proceed to Question 4

☐ Patient has changed from NPWT to Usual Care **since the last assessment**
If 'Yes', proceed to Question 4

☐ Patient has changed from Usual Care to NPWT **since the last assessment**
If 'Yes', proceed to Question 4

4. Please indicate why the patient has had changes made since the last assessment *(cross all that apply)*:

☐ Wound improving ☐ Wound healed ☐ Wound bed prepared

☐ Wound too dry ☐ Deterioration of wound ☐ Failure to maintain seal

☐ Treatment caused pain ☐ No change to wound

☐ Other (please specify): _____

Was the change at: ☐ Patient request ☐ Clinician request

If participant is receiving NPWT, proceed to Section C

If participant is receiving Usual Care, proceed to Section D

Section C – Changes to NPWT Treatment Please only complete if you have selected 3c or 3f

Please provide date change made: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

Please provide details of the NPWT treatment the patient is now receiving *(select one option)*:

1. ☐ V.A.C Ulta (KCl)
☐ V.A.C Via (KCl)
☐ InfoV.A.C (KCl)
☐ ActiV.A.C (KCl)
☐ Renasys (Smith and Nephew)
☐ PICO (Smith and Nephew)
☐ Avance (Molnlycke Health Care)
☐ Avance Solo (Molnlycke Health Care)
☐ Avelle (Convatec)
☐ Other (please specify model and brand):

2. Amount of pressure being used: ☐☐☐ *mmHg*

3. Is the pressure being applied: ☐ Continuously ☐ Intermittently

4. Type of NPWT dressing being used:
☐ Black, polyurethane foam dressings with reticulated (open) pores
☐ White, polyvinyl alcohol with high tensile strength, pre-moistened with sterile water
☐ Antimicrobial gauze (impregnated with Polyhexamethylene biguanide)

5. Has a liner been used with the dressing? ☐ Yes ☐ No

a) If 'Yes', was the liner silver impregnated? ☐ Yes ☐ No

Please proceed to Section E

Section D – Changes to Usual Care Treatment Please only complete if you have selected 3d or 3e

Please provide date change made: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

Please provide details of the Usual Care treatment the patient is now receiving *(cross all that apply)*:

☐ Alginate
☐ Basic wound contact
☐ Cavity Foam
☐ Foam
☐ Gauze Ribbon
☐ Hydrocolloid
☐ Hydrogel
☐ Hydrofoam/Spun Hydrocolloid
☐ Honey
☐ Iodine Containing
☐ PHMB
☐ Protease Modulating matrix
☐ Silver containing
☐ Flamazine silver sulfadiazine dressing
☐ Urgotol silver sulfadiazine dressing
☐ Soft polymer
☐ Superabsorbent
☐ Vapour permeable film or membrane
☐ Other (please specify):
☐ Other (please specify):

Please proceed to Section E

Section E – Other Treatments

1. Is the participant currently using antibiotics? ☐ Yes ☐ No

a) If 'Yes', please indicate the route of administration:

☐ IV ☐ Oral ☐ Other (please specify): _____

b) If 'Yes', please indicate the reason:

☐ Related to SWHSI ☐ Other (please specify): _____

2. Is the participant receiving any other treatment for their SWHSI? ☐ Yes ☐ No

a) If 'Yes', please provide details below *(cross all that apply)*:

☐ Wound Management Systems ☐ Emollient ☐ Silver Nitrate Stick

☐ Dietetic Input ☐ Larvae

☐ Other (please specify): _____

☐ Other (please specify): _____

☐ Other (please specify): _____

Please proceed to Section F

Section F – Visit Checklist and Sign Off

1. All Sections of the Weekly Assessment are complete? ☐ Yes ☐ No

2. Has the next weekly assessment (or first post wound healing visit if wound has healed) been arranged? ☐ Yes ☐ No

Form Completed by (to be completed by delegated clinician or nurse who has reviewed CRF content for this visit)

*Name: _____

Signature: _____

Assessor ID: ☐☐

Date: ☐☐ / ☐☐ / ☐☐☐☐
day *month* *year*

*Must be reflected in the Delegation of Duties Log