CONFIDENTIAL WHEN COMPLETED

SUNRRISE Trial
Patient Discontinuation Form

Birmingham Clinical Trials Unit

SUNRRISE Trial Number:	☐☐☐☐☐
Patient Initials: ☐☐☐	Site name: _____
Date of discontinuation:	D D M M M Y Y Y Y

Please indicate the consent in place/circumstances at the time of discontinuation and then complete the sections as directed:	**Complete sections:**
Informed Consent Form (Standard or Delayed) has been completed by the patient ☐	→ **A & B**
Consultee Declaration/Representative Consent Form completed only and patient has not regained capacity ☐	→ **C & D**
Consultee Declaration/Representative Consent Form completed only and patient has regained capacity ☐	→ **E**

SECTION A - Type of discontinuation where patient consent (standard/delayed) obtained

Who made the decision for discontinuation of the patient from the trial?

Patient ☐ Principal or other Investigator (doctor) ☐ Both ☐

Please provide a response to all questions to clearly indicate the patient's discontinuation.		**No**	**Yes**
a.	Discontinuing trial treatment? *e.g. allocated dressing to be removed*	☐	☐
b.	Discontinuing follow-up according to the protocol schedule of assessments? *e.g. will not attend 30 day visit*	☐	☐
c.	Discontinuing with completion of health related quality of life questionnaire (EQ-5D-5L & SF-12)?	☐	☐
d.	Discontinuing with completion of the Patient Diary?	☐	☐
e.	Discontinuing with completion of the Wound Health Questionnaire?	☐	☐
f.	Discontinuing with completion of the Patient Diary (Continuing Involvement)? *'Continuing Involvement' diary is only applicable to patients with an ongoing SSI at the 30 day assessment.*	☐	☐

In all instances, please provide the reason for the discontinuation below (if the patient did not give a reason, please state this):

_____

_____

_____

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SECTION B - Data collection status where patient consent (standard/delayed) obtained

Where all **future** active involvement in the trial is discontinued, please clarify the data collection wishes.	**No**	**Yes**
Is the patient willing for their data collected routinely by the NHS (e.g. hospital medical notes/records), including data held by NHS Digital, to be accessed for providing information related to the outcomes of the trial and their long term health status and health care? ***There will be no expectation or requirement for the patient to be involved or provide data directly themselves. Research staff involved in SUNRRISE will review the patient's medical records, held locally or nationally, to obtain data relevant to the trial.***	☐	☐
↳ If **No**, is the patient willing for their data only held by NHS Digital to be accessed for providing information relating to their long term health status and health care?	☐	☐

The Trial Office will advise on completing further CRF, based on when discontinuation occurs and the response to Section B.

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SECTION C – Type of discontinuation if only consultee declaration/representative consent obtained.

Who made the decision for discontinuation of the patient from the trial?

Consultee/representative ☐ Principal or other Investigator (doctor) ☐ Both ☐

Please provide a response to all questions to clearly indicate the patient's discontinuation.		No	Yes
a.	Discontinuing trial treatment? *e.g. allocated dressing to be removed*	☐	☐
b.	Discontinuing follow-up according to the protocol schedule of assessments? *e.g. not attend 30 day visit*	☐	☐

In all instances, please provide the reason for the discontinuation below (if the consultee/representative did not give a reason, please state this):

_ _

_ _

_ _

_ _

SECTION D - Data collection status if only consultee declaration/representative consent obtained.

Where all future active involvement in the trial is discontinued, please clarify the data collection wishes.	No	Yes
Is the consultee/representative willing for their friend's/relative's data collected routinely by the NHS (e.g. hospital medical notes/records), including data held by NHS Digital, to be accessed for providing information related to the outcomes of the trial and their long term health status and health care? ***There will be no expectation or requirement for the patient to be involved or provide data directly themselves. Research staff involved in SUNRRISE will review the patient's medical records, held locally or nationally, to obtain data relevant to the trial.***	☐	☐
↳ If **No**, is the consultee/representative willing for their friend's/relative's data only held by NHS Digital to be accessed for providing information relating to their long term health status and health care?	☐	☐

The Trial Office will advise on completing further CRF, based on when discontinuation occurs and the response to Section B.

SECTION E - Discontinuation if only consultee declaration/representative consent obtained AND when participant regained capacity they did not wish to take part in the study.

If patient provided a reason for their decision not to take part, please give below (if the patient did not give a reason, please state this):

_ _

_ _

_ _

_ _

Form completed by:

Full Name: **(PRINT NAME)**	**Position:**
Signature:	**Date form completed:** D D M M M Y Y Y Y

PI declaration – I can confirm that the data featured on this form are accurate:

Full Name: **(PRINT NAME)**	
Signature:	**Date form signed by PI:** D D M M M Y Y Y Y

Thank you for completing this CRF. Please return the original to SUNRRISE Trial Office, Birmingham Clinical Trials Unit (BCTU), Public Health Building, University of Birmingham, Edgbaston, Birmingham, B15 2TT

FOR TRIALS OFFICE USE ONLY:

Received		Entered		Checked	
Date:	Initials:	Date:	Initials:	Date:	Initials: