CONFIDENTIAL WHEN COMPLETED

SUNRRISE Trial

Wound Assessment Day 7 or on Discharge (if sooner)

SUNRRISE Trial Number:			
Patient Initials:		Date of assessment:	D D M M M Y Y Y Y
Site name: _		Is the date of assessment also the date of discharge?	No ☐ Yes ☐

PART A – Wound Dressing		
	No	**Yes**
Did the patient have a SUNPD dressing applied at the end of surgery? **If 'No', go to straight to Part B**	☐	☐
Since surgery was undertaken:	**No**	**Yes**
Has the patient experienced a skin reaction to the dressing?	☐	☐
Has the patient experienced any pain/discomfort related to the dressing?	☐	☐
Was the SUNPD dressing changed for another SUNPD dressing before the 7th post-op day?	☐	☐
↳ If **Yes**, on what date was the dressing changed?	D D M M M Y Y Y Y	
↳ If **Yes**, please select the reason: (Please select only one)	Dressing leak ☐ Suspected SSI ☐ Dressing came away ☐ Saturated dressing requiring change ☐ Routine wound check ☐ Other (please specify) _ _ _ _ _ _ _ _ _ _ _ _ _ _	
On what date was the final SUNPD removed and replaced with a 'standard dressing/no dressing'?	D D M M M Y Y Y Y	
What was the reason for the removal of the SUNPD and replacement with a 'standard dressing/no dressing'? (Please select only one) End of SUNPD treatment (Day 7 or discharge if sooner) ☐ Patient choice ☐ If ticked, please provide details: _ SUNPD dressing unavailable ☐ Other ☐ If ticked, please specify: _		

PART B – Wound Review: Infection		
Since surgery was undertaken: (please answer by asking the patient and assessing the wound)	**No**	**Yes**
Has there been purulent drainage from the incision?	☐	☐
Have organisms been detected from wound swabs from the incision?	☐	☐
Has an SSI been diagnosed by a clinician or by imaging?	☐	☐
Has the wound spontaneously opened or been opened by a clinician?	☐	☐
Have any of the following symptoms and signs been detected:	**No**	**Yes**
• Pain or tenderness at the incision site?	☐	☐
• Localised swelling?	☐	☐
• Redness at the incision site?	☐	☐
• Heat at the incision site?	☐	☐
• Fever (>38°C)?	☐	☐
↳ If the patient had a wound infection, what management did they receive? (Please tick all that apply) None / conservative management ☐ Antibiotic drug treatment ☐ Surgical intervention ☐ *If ticked and was in theatre, please complete a Return to Theatre form for <u>each</u> visit.* On ward intervention ☐ Radiological intervention ☐ ITU admission ☐ *If ticked, please complete an SAE form.*		
↳ If the patient had a wound infection, did it prolong their hospitalisation?	No ☐ Yes ☐ → If **Yes**, for how many days? ___ days	

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Wound Assessment Day 7 or on Discharge (if sooner)

Birmingham Clinical Trials Unit

PART C – Wound Review: Other complications

Has there been any *other* wound complications (excluding wound infection)? No ☐ Yes ☐

↳ If **Yes**, please add the appropriate management/intervention code (A-F – see grey shaded box) for the corresponding complication(s) *e.g. for dehiscence re-sutured at the bedside, add "B" to box next to "dehiscence"*

Granuloma ☐ Haematoma ☐ Other ☐ If other, please specify below:

Seroma ☐ Dehiscence ☐ _____

A	None / conservative management	**C**	Antibiotic drug treatment	**E**	Surgical intervention → *If code used and was in theatre, please complete a Return to Theatre form for each visit.*
B	On ward intervention	**D**	Radiological intervention	**F**	ITU admission → *If code used, please complete an SAE form.*

↳ If **Yes**, did it prolong their hospitalisation? No ☐ Yes ☐ → If **Yes**, for how many days? ___ days

PART D – Serious Adverse Events

The following events are regarded as SAEs but are not subject to expedited reporting since they are expected potential complications of an emergency laparotomy.

Has the patient had any of the following complications following surgery?	No	Yes
• An anastomotic leak (diagnosed either radiologically or at re-operation)	☐	☐
• An intra-peritoneal collection (with or without intervention)	☐	☐
• A thrombo-embolic event? (e.g. DVT or PE)	☐	☐
• An infection not related to the wound (e.g. pneumonia, urinary tract infection)	☐	☐
• A cardiac or central nervous system complication	☐	☐
• Paralytic ileus	☐	☐

PART E – To be asked of the patient

Please ask the patient to score the **acceptability** of the type of dressing that was applied to their primary laparotomy wound. Please circle the appropriate number (**1** being **completely acceptable**, **10** being **totally unacceptable**)

Completely acceptable 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10 **Totally unacceptable**

Please ask the patient to score the **pain** they are experiencing at the site of their primary laparotomy. Please circle the appropriate number (**1** being **no pain at all**, **10** being the **worst possible pain**)

No pain at all 1 - 2 - 3 - 4 - 5 - 6 - 7 - 8 - 9 - 10 **Worst possible pain**

PART F – Quality of life

SF-12 and EQ-5D questionnaires should be completed on Day 7

Primary laparotomy wound review performed by and form completed by:

Full Name: (PRINT NAME)	**Position:**
Signature:	**Date:** 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:** 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: