CONFIDENTIAL WHEN COMPLETED

SUNRRISE Trial
Wound Assessment on Day 30

Form to be completed by a wound assessor blind to the patient's allocation

SUNRRISE Trial Number:			
Patient Initials:		Date of assessment:	D D M M M Y Y Y Y
Site name: _____			
Has the patient been discharged?	No ☐ Yes ☐ → Discharge date:		D D M M M Y Y Y Y
Since the day of surgery, has the patient had:	A proven SARS-CoV-2 infection	No ☐	Yes ☐
	A clinical diagnosis of COVID-19	No ☐	Yes ☐
Is the primary laparotomy wound reviewer fully blinded to the patient's treatment allocation?		No ☐	Yes ☐

↳ If **No**, please provide the details and reason for the deviation in a file note (or equivalent e.g. DCF, annotation or within Part C)

PART A – Wound Review: Infection

In the 30-day period following surgery: (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 each visit.*

On ward intervention ☐ | Radiological intervention ☐ | ITU admission ☐ *If ticked, please complete an SAE form.*

↳ If the patient had a wound infection, as a result:

- Was their initial hospitalisation **prolonged**? No ☐ Yes ☐ → If **Yes**, for how many days? ___ days
- Were they **re-admitted** to hospital? No ☐ Yes ☐ → If **Yes**, for how many days? ___ days

↳ If the patient had a wound infection, is it ongoing? ***If YES** (ongoing), please provide the patient with a "Continuing Involvement" Diary and ask them to complete it until their wound has healed.* No ☐ Yes ☐

PART B – Wound Review: Other complications

Has there been any *other* wound complications (excluding wound infection) in the 30-day period following surgery? 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**, as a result:

- Was their initial hospitalisation prolonged? No ☐ Yes ☐ → If **Yes**, for how many days? ___ days
- Were they re-admitted to hospital? No ☐ Yes ☐ → If **Yes**, for how many days? ___ days

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PART C – Wound Review: Method and timing

The **protocol** requires wound review be undertaken **in-person** or **by remote video consultation** at **30-44 days** post-operatively. If this is not achieved, either in how the review is completed or when it is done, the details and reasons for the deviation need to be documented.

How was the review conducted?

- ☐ **In-person** with visualisation of wound
- ☐ Remotely with visualisation of wound by **video call**
- ☐ Remotely without visualisation of wound by **telephone call** → *Please explain why below*
- ☐ Other → If **Other**, please specify:_____ → *Please explain why below*

↳ If NOT conducted **as required in the protocol**, please explain why:_____

Was the wound review completed in the window **required in the protocol**? No ☐ Yes ☐

↳ If NOT conducted **when required in the protocol**, please explain why:_____

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 – Wound Heath Questionnaire (to be asked of the patient)

This is a repeat of the questionnaire in the diary. Please ask the questions and give options to the patient. Under each heading, please tick the ONE box that is most relevant to their experience.

Since you left hospital after having surgery....		Not at all	A little	Quite a bit	A 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. a.	Have the edges of any part of the wound separated/gaped open on their own accord? (spontaneous dehiscence)	☐	☐	☐	☐
	Please answer this next question only if you have said the edges of the wound separated/gaped open				
6. b.	Did the deeper tissue also separate?	☐	☐	☐	☐

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Since you left hospital after having surgery....		Not at all	A little	Quite a bit	A lot
7.	Has the area around the wound become swollen?	☐	☐	☐	☐
8.	Has the wound been smelly?	☐	☐	☐	☐
9.	Has the wound been painful to touch?	☐	☐	☐	☐
10.	Have you had, or felt like you have had, a raised temperature or fever (fever >38°C)	☐	☐	☐	☐

Since you left hospital after having surgery....		No	Yes
11.	Have you sought advice because of a problem with your wound, other than at a planned follow-up appointment?	☐	☐
12.	Has anything been put on the skin to cover the wound? (dressing)	☐	☐
13.	Have you been back into hospital for treatment of a problem with your wound?	☐	☐
14.	Have you been given antibiotics for a problem with your wound?	☐	☐
15.	Have the edges of your wound been deliberately separated by a doctor or nurse?	☐	☐
16.	Has your wound been scraped or cut to remove any unwanted tissue? (debridement of wound)	☐	☐
17.	Has your wound been drained? (drainage of pus / abscess)	☐	☐
18.	Have you had an operation under general anaesthetic for treatment of a problem with your wound?	☐	☐

PART F – Wound Pain (to be asked of the patient)

Please ask the patient to score the **pain** they are experiencing at the site of their primary laparotomy wound.
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 G - Quality of life

SF-12 and EQ-5D questionnaires should be completed on Day 30.

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: