CONFIDENTIAL WHEN COMPLETED

SUNRRISE Trial
Return to Theatre Form

Birmingham Clinical Trials Unit

(This form should be completed for all patients who return to theatre within 30 days post randomisation)

SUNRRISE Trial Number: ☐☐☐☐☐	
Patient Initials: ☐☐☐	Date of return to theatre: D D M M M Y Y Y Y
Site name:	

On return to theatre:	**Yes**	**No**
Was the laparotomy wound re-opened? If "NO" *you do not need to further complete the form*	☐	☐
Was the indication a wound infection?	☐	☐
↳ If the indication for the re-opening was <u>not</u> a wound infection, what was the reason:	**Yes**	**No**
• Anastomotic leak	☐	☐
• Intra-abdominal sepsis	☐	☐
• Bleeding	☐	☐
• Planned-relook	☐	☐
• Other, please provide details: _		

Before or during the operation:	**Yes**	**No**
Has there been purulent drainage from the incision?	☐	☐
Have organisms been detected from wound swabs from the wound?	☐	☐
Has an SSI been diagnosed by a clinician or on imaging?	☐	☐
Has the wound been opened by a clinician and/or has it spontaneously opened?	☐	☐
Have any of the following symptoms and signs been detected:	**Yes**	**No**
• Pain or tenderness at the incision site?	☐	☐
• Localised swelling?	☐	☐
• Redness at the incision site?	☐	☐
• Heat at the incision site?	☐	☐
• Fever (>38°C)?	☐	☐

As the patient has returned to theatre, please consider if the event meets the definition of an SAE (see section 9 of the protocol).

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 completed:** D D M M M Y Y Y Y

Thank you for completing this CRF. Please return the <u>original</u> 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: