

SUNRRRISE Trial Randomisation Form

Please complete all parts of this paper form prior to randomisation.

To randomise log on to <https://w3.abdn.ac.uk/hsru/SUNRRRISE>, or alternatively telephone **0800 2802 307**.

The box immediately below collates the information required to complete the randomisation process. Once completed, a confirmation email will be sent to the site PI, nominated nursing contact and, where possible, the person performing the randomisation.

When you log on to or call the randomisation service, have the following information ready:

Centre/Site ID code:	<input type="text"/>	Date of Birth:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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Eligibility Checklist: If any shaded boxes are ticked, the patient is NOT ELIGIBLE for inclusion		No	Yes
1.	Has the patient undergone an emergency (non-elective) laparotomy?	<input type="checkbox"/>	<input type="checkbox"/>
2.	Is the patient at least 16 years old?	<input type="checkbox"/>	<input type="checkbox"/>
3.	Was the incision at least 5cm?	<input type="checkbox"/>	<input type="checkbox"/>
4.	Is the skin closure primary?	<input type="checkbox"/>	<input type="checkbox"/>
5.	Has the patient/consultee/representative given consent/assent by signing the SUNRRRISE-specific consent/declaration form?	<input type="checkbox"/>	<input type="checkbox"/>
6.	Is the patient willing and able to attend follow-up at 30 days?	<input type="checkbox"/>	<input type="checkbox"/>
7.	Has the patient had abdominal surgery within the last three months?	<input type="checkbox"/>	<input type="checkbox"/>
8.	Is a return to theatre for reopening of the laparotomy wound expected within 30 days?	<input type="checkbox"/>	<input type="checkbox"/>

During randomisation you will be asked a single question to confirm the patient is eligible, as indicated by none of the shaded boxes above being ticked.

If any of the shaded boxes for questions 1 to 8 are ticked, the patient is NOT ELIGIBLE to be randomised into SUNRRRISE

Is the patient eligible to be randomised into SUNRRRISE?	No <input type="checkbox"/>	Yes <input type="checkbox"/>
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Operative details:

What degree of operative field contamination was found?			
Clean <input type="checkbox"/> <i>Uninfected, no inflammation. GI/ GU tracts not entered.</i>	Clean-contaminated <input type="checkbox"/> <i>GI/ GU tracts entered in a controlled manner with no unusual contamination.</i>	Contaminated <input type="checkbox"/> <i>Open, fresh, accidental wounds. Major break in sterile technique. Gross Spillage from GI tract. Acute non-purulent inflammation.</i>	Dirty <input type="checkbox"/> <i>Old traumatic wounds. Devitalized tissue. Existing infection or perforation. Organisms present BEFORE procedure.</i>
Is a stoma present?	Yes (pre-existing) <input type="checkbox"/>	Yes (formed during this operation) <input type="checkbox"/>	No <input type="checkbox"/>

Randomisation:

SUNRRRISE Trial Number:	<input type="text"/>
Allocation:	<div>Control (surgeon's preference of standard dressing) <input type="checkbox"/> → Another type of negative pressure, honey, iodine or silver dressings cannot be applied to the wound</div> <div>Single-use negative pressure dressing (SUNPD) <input type="checkbox"/> → Glue cannot be applied to the wound</div>

PLEASE CONTINUE ONTO THE NEXT PAGE.

The BASELINE DATA overleaf should be completed PRIOR TO SURGERY. If this is not possible, it should be completed immediately after surgery.

CONFIDENTIAL WHEN COMPLETED

Identifying Details	
Patient forename(s):	Patient sex: Male <input type="checkbox"/> Female <input type="checkbox"/>
Patient surname:	NHS/CHI No: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Confirmation of Eligibility	
SUNRRISE eligibility <u>must</u> be confirmed by a medically trained individual (Doctor). By signing this form, the named clinician confirms that the information provided on this document is true and that this patient fulfils all necessary criteria for inclusion into the SUNRRISE trial.	
Name of medically qualified doctor confirming eligibility for entry into the trial:	
Signature of medically qualified doctor confirming eligibility for entry into the trial:	
Date eligibility was confirmed:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Quality of Life	
Has the patient completed the Quality of Life questionnaires (SF-12 and EQ-5D), which should be completed prior to surgery?	No <input type="checkbox"/> Yes <input type="checkbox"/>
↳ If No, please explain why not? _____	

Baseline Data			
BMI: <input type="text"/> <input type="text"/> <input type="text"/> If BMI is <u>not</u> available, please provide:	Height (in cm): <input type="text"/> <input type="text"/> <input type="text"/>	Weight (in kg): <input type="text"/> <input type="text"/> <input type="text"/>	
Serum albumin level (in g/L): <input type="text"/> <input type="text"/>	(Expected ranged: 20-50 Max range: 5-80)		
Does the patient have known diabetes?	No <input type="checkbox"/> Yes <input type="checkbox"/>		
↳ If Yes, how is it managed: (tick all that apply)	Diet-controlled <input type="checkbox"/>	Tablets <input type="checkbox"/>	Insulin <input type="checkbox"/>
What is the patient's smoking status? (E-cigarette use is not considered smoking)	Never smoked <input type="checkbox"/>	Current smoker (or stopped smoking ≤6 weeks ago) <input type="checkbox"/>	Ex-smoker (stopped smoking > 6 weeks ago) <input type="checkbox"/>
Is the patient on any immunosuppressive therapy? (oral or inhaled immunosuppressive medication including steroids, or immunosuppressed due to pre-existing medical condition)	No <input type="checkbox"/> Yes <input type="checkbox"/>		
Is the patient clinically jaundiced? (or serum bilirubin >50 µmol/L)	No <input type="checkbox"/> Yes <input type="checkbox"/>		
Does the patient have an active malignancy? (does not have to be the condition being operated on)	No <input type="checkbox"/> Yes <input type="checkbox"/>		

Form completed by:	
Full Name: (PRINT NAME)	Position:
Signature:	Date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

PI declaration – I can confirm that the data featured on this form are accurate:	
Full Name: (PRINT NAME)	
Signature:	Date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

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: