TRIAL ID: ☐☐☐☐☐ | Initials: F M L | Site ID: ____________

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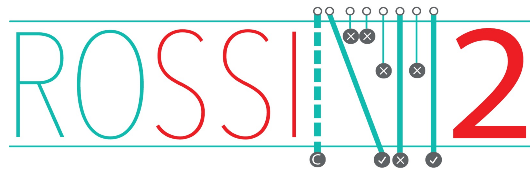

RETURN TO THEATRE FORM

This form should be completed for all patients who return to theatre within 30 days post surgery.

Date of return to theatre: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

PART A - On return to theatre

Was the abdominal wound re-opened? *(If No, you do not need to further complete this form)*
◯ No
◯ Yes

If Yes, did/ does the patient have a wound infection? ◯ No ◯ Yes

If the primary indication for the re-opening was not a wound infection, what was the reason? *(Tick all that apply)*

Anastomotic leak	◯ No	◯ Yes
Intra-abdominal sepsis	◯ No	◯ Yes
Bleeding	◯ No	◯ Yes
Planned relook	◯ No	◯ Yes
Other	◯ No	◯ Yes

If other, please specify?

____

____

PART B - Before or during the operation

Has there been purulent drainage from the incision?	◯ No	◯ Yes
Have organisms been detected from swabs of the wound?	◯ No	◯ Yes
Has an SSI been diagnosed by a clinician or on imaging?	◯ No	◯ Yes
Has the wound been opened by a clinician and/or has it spontaneously opened?	◯ No	◯ Yes

PART C - Symptoms

Have any of the following symptoms and/or signs been detected: *(Please tick No or Yes)*

Pain or tenderness at the incision site?	◯ No	◯ Yes
Localised swelling?	◯ No	◯ Yes
Redness at the incision site?	◯ No	◯ Yes
Heat at the incision site?	◯ No	◯ Yes
Fever greater than 38°C?	◯ No	◯ Yes

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

TRIAL ID:	Initials: F M L	Site ID:

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Completed by:

Full Name: *(PRINT NAME)*	Position:
Signature:	Date: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

PI or Delegated Local Investigator Declaration

I can confirm that data featured on this form are accurate:

Full Name: *(PRINT NAME)*	
Signature:	Date: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

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

FOR ROSSINI 2 TRIALS OFFICE USE ONLY:

Received by:	Entered by:	Checked by:
Date: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y	Date: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y	Date: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y