TRIAL ID: | Initials: F M L | Site ID: _____

UNIVERSITY OF BIRMINGHAM

BCTU Birmingham Clinical Trials Unit

ROSSINI 2

WOUND ASSESSMENT FORM

To be completed on **Day 7** (+/- 2 days) or discharge if sooner.

PART A - Patient Status

Has the patient died? ◯ No ◯ Yes | If Yes, Date of death: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Primary cause of death: _____

If the patient died, please complete a SAE Form only if related to the wound or trial intervention(s).

PART B - Wound Assessment

Date of assessment: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

Is the date of assessment also the date of discharge or within one day? ◯ No ◯ Yes

If this wound assessment was not carried out within the correct timeframe (Day 7 (+/- 2 days) or discharge if sooner), please explain why:

_____

_____

_____

Review of primary, abdominal wound performed by? *(PRINT NAME)*

_____

Is the wound reviewer fully blinded to the patient's treatment allocation? *(If No, please complete a Protocol Non-Compliance Form)* ◯ No ◯ Yes

How was this assessment of the wound conducted: *((Please tick No or Yes to all)*

Face to face	◯ No	◯ Yes
Via video teleconferencing	◯ No	◯ Yes
Over the telephone	◯ No	◯ Yes
Other (If other, please specify _____)	◯ No	◯ Yes

PART C - Day 7 Wound Review: **INFECTION**

Please answer by asking the patient and assessing the wound.

Since surgery was undertaken:

Has there been purulent drainage from the incision? ◯ No ◯ Yes

Have organisms been detected from wound swabs from the incision? ◯ No ◯ Yes

Has an SSI been diagnosed by a clinician or by imaging? ◯ No ◯ Yes

Has the wound spontaneously opened or been opened by a clinician? ◯ No ◯ Yes

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

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

In your opinion, has the patient had a wound infection? *(Please tick one. If Yes is ticked, please continue to the next question)* ◯ No ◯ Yes

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If the patient has/had a wound **infection**, what management was required? *(Please tick No or Yes to all)*

None	◯ No	◯ Yes
On ward intervention	◯ No	◯ Yes
Antibiotic drug treatment	◯ No	◯ Yes
Radiological intervention	◯ No	◯ Yes
Surgical intervention *(If ticked, please complete a Return to Theatre Form for <u>each</u> visit)*	◯ No	◯ Yes
ITU admission	◯ No	◯ Yes

If the patient has/ had a wound **infection**, did it prolong their hospitalisation? ◯ No ◯ Yes ◯ Not Sure

PART D - Day 7 Wound Review: OTHER COMPLICATIONS

Has there been any *other* wound **complication(s)** (excluding wound infection)? ◯ No ◯ Yes

If Yes, please add the appropriate management/ intervention code (A-F - See definitions below) in the box next to the corresponding complication(s).

Granuloma ☐	Haematoma ☐	Seroma ☐
Dehiscence ☐	Other *(If Other, Please Specify _____)* ☐	

A - None

B - On ward intervention

C - Antibiotic drug treatment

D - Radiological intervention

E - Surgical intervention *(If code used, please complete a Return to Theatre Form for <u>each</u> visit.)*

F - ITU Admission

If the patient has/ had any of the above wound **complication(s)**, did it prolong their hospitalisation? ◯ No ◯ Yes ◯ Not Sure

PART E - Serious Adverse Events

The following events are regarded as SAEs but are **<u>not</u>** subject to expedited reporting since they are expected potential complications of abdominal surgery/ laparotomy.

Has the patient had any of the following complications following surgery? *(Please tick No or Yes to all)*

An anastomotic leak	◯ No	◯ Yes
An intra-peritoneal collection (with or without intervention)	◯ No	◯ Yes
A thrombo-embolic event (eg DVT or PE)	◯ No	◯ Yes
An infection not related to the wound (eg pneumonia or UTI)	◯ No	◯ Yes
A cardiac or central nervous complication	◯ No	◯ Yes
Paralytic ileus	◯ No	◯ Yes

PART F - Questionnaire

Has the patient completed an EQ-5D questionnaire? ◯ No ◯ Yes

If No, please specify why not:

_____

_____

PLEASE NOTE: Details of the patient's COVID-19 status (in the post operative period) will be asked at the Day 30 Assessment.

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

Thank you for completing this CRF. You are now required to transcribe this information onto REDCap (https://bctu-redcap.bham.ac.uk/). This CRF can be used as source documentation and filed in the patient's records.