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

UNIVERSITY OF BIRMINGHAM

BCTU Birmingham Clinical Trials Unit

ROSSINI 2

WOUND ASSESSMENT FORM

To be completed between **Day 30 - 37**

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

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

If this wound assessment was not carried out within the correct timeframe (day 30-37), please explain why:

_____

_____

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

Has the patient been discharged from hospital? ◯ No ◯ Yes | If Yes, Please provide date of discharge: *e.g. 31-JAN-2017* D D - M M M - Y Y Y Y

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 30 - 37 Wound Review: **INFECTION**

To be answered by asking the patient and assessing the wound.

Since the last wound assessment, or if no previous wound assessment then since surgery:

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 - Resolved ◯ Yes - Ongoing

Please notify the ROSSINI 2 Trials Team if you have answered 'Yes - Ongoing'.

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If the patient 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

Since discharge from hospital:

If the patient had a wound **infection**, were they re-admitted to hospital as a result? ◯ No ◯ Yes ◯ Not Sure

If Yes, by how many days? ___ ___ ___ days

PART D - Day 30 - 37 Wound Review: **COMPLICATION**

Has there been any *other* wound **complication(s)** (excluding wound infection) since the last wound assessment, or if no previous wound assessment then since surgery?

◯ 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 had any of the above wound **complication(s)**, were they re-admitted to hospital as a result? ◯ No ◯ Yes

If Yes, how many days? ___ ___ ___ days

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 since the last wound assessment, or if no previous wound assessment then since 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

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PART F - Questionnaires

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

If No, please specify why not:

Has the patient completed a Wound Healing Questionnaire (WHQ)? ◯ No ◯ Yes

If No, please specify why not:

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.