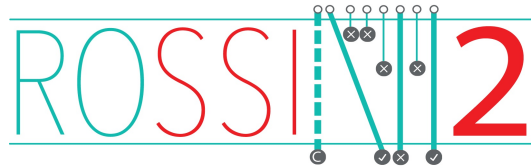


TRIAL ID: [][][][][]

Initials: [F] [M] [L]

Site ID: _____



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 - 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 - 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 - 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'.

TRIAL ID: <input type="text"/>	Initials: <input type="text"/>	Site ID: <input type="text"/>
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If the patient had a wound **infection**, what management was required? (Please tick No or Yes to all)

None	<input type="radio"/> No	<input type="radio"/> Yes
On ward intervention	<input type="radio"/> No	<input type="radio"/> Yes
Antibiotic drug treatment	<input type="radio"/> No	<input type="radio"/> Yes
Radiological intervention	<input type="radio"/> No	<input type="radio"/> Yes
Surgical intervention (If ticked, please complete a Return to Theatre Form for <u>each</u> visit)	<input type="radio"/> No	<input type="radio"/> Yes
ITU admission	<input type="radio"/> No	<input type="radio"/> 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 <input type="checkbox"/>	Haematoma <input type="checkbox"/>	Seroma <input type="checkbox"/>
Dehiscence <input type="checkbox"/>	Other (If Other, Please Specify _____) <input type="checkbox"/>	

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 each 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 **not** 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	<input type="radio"/> No	<input type="radio"/> Yes
An intra-peritoneal collection (with or without intervention)	<input type="radio"/> No	<input type="radio"/> Yes
A thrombo-embolic event (eg DVT or PE)	<input type="radio"/> No	<input type="radio"/> Yes
An infection not related to the wound (eg pneumonia or UTI)	<input type="radio"/> No	<input type="radio"/> Yes
A cardiac or central nervous complication	<input type="radio"/> No	<input type="radio"/> Yes
Paralytic ileus	<input type="radio"/> No	<input type="radio"/> Yes

PART F - COVID 19, Post-surgery

Since the day of surgery, has the patient had: (Please tick one)

A proven SARS-CoV-2 infection	<input type="radio"/> No	<input type="radio"/> Yes
A clinical diagnosis of COVID-19	<input type="radio"/> No	<input type="radio"/> Yes

TRIAL ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Initials: <input type="text"/> F <input type="text"/> M <input type="text"/> L	Site ID: _____
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PART G - 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)

Position:

Signature:

Date: e.g. 31-JAN-2017 - -

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.