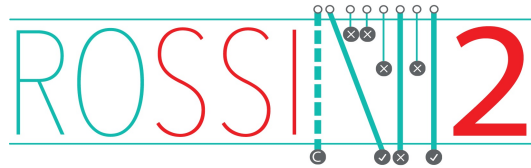


TRIAL ID: <input type="text"/>	Initials: <input type="text"/> <input type="text"/> <input type="text"/>	Site ID: <input type="text"/>
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WOUND ASSESSMENT FORM

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 - -

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 - - 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	<input type="radio"/> No	<input type="radio"/> Yes
Via video teleconferencing	<input type="radio"/> No	<input type="radio"/> Yes
Over the telephone	<input type="radio"/> No	<input type="radio"/> Yes
Other (If other, please specify _____)	<input type="radio"/> No	<input type="radio"/> 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?	<input type="radio"/> No	<input type="radio"/> Yes
Localised swelling?	<input type="radio"/> No	<input type="radio"/> Yes
Redness at the incision site?	<input type="radio"/> No	<input type="radio"/> Yes
Heat at the incision site?	<input type="radio"/> No	<input type="radio"/> Yes
Fever greater than 38°C?	<input type="radio"/> No	<input type="radio"/> 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

TRIAL ID: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Initials: <input type="text"/> <input type="text"/> <input type="text"/>	Site ID: <input type="text"/>
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If the patient has/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

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 <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 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 **not** 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	<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 - 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 - -

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.