ROCSS-EX

Clinical Follow-up Form (CRF1)

This form can be used to collate data for entry onto the ROCSS-EX REDCap database. Alternatively, data can be entered directly onto the database.

PATIENT RECORD

Trial Number: ☐☐☐☐

Hospital No.: ☐☐☐☐☐☐☐☐☐☐☐☐   NHS No.: ☐☐☐☐☐☐☐☐☐☐

Randomisation Date: D D - M M - Y Y Y Y   Surgery (reversal) Date: D D - M M - Y Y Y Y

The ROCSS-EX database contains list of patients to be followed up - you will only be able to see patients from your hospital.

The records will also contain the details listed above, which will aid you to identify the patient in the local hospital records.

Is the patient still alive?   ○ Yes   ○ No

If the patient has died: 1) telephone follow-up cannot be completed; 2) check database to see if clinical follow-up can be completed.

➡ If 'Yes', has the patient been contacted (i.e. there has been a response from the patient)?   ○ Yes   ○ No

If the patient cannot be contacted (lost to follow-up): 1) telephone follow-up cannot be completed; 2) check database to see if clinical follow-up can be completed; 3) details of why and efforts made are to be added to the database.

➡ If 'Yes', when contacted, did the patient agree to participation in ROCSS-EX?   ○ Yes   ○ No

If the patient did not agree to participate in ROCSS-EX: 1) telephone follow-up cannot be completed; 2) check database to see if clinical follow-up can be completed.

CLINICAL FOLLOW-UP QUESTIONS

Date follow-up completed: D D - M M - Y Y Y Y

The following questions should be answered using the patient's medical records

Is the patient still alive?   ○ Yes   ○ No   ➡   If 'No', date of death: D D - M M - Y Y Y Y

Date of discharge following the stoma reversal operation?   D D - M M - Y Y Y Y

Section 1 - SYMPTOMS RELATING TO THE STOMA CLOSURE SITE

Has the patient been readmitted to hospital due to abdominal symptoms thought to be related to their stoma closure site since their operation?   ○ Yes   ○ No

➡ If 'Yes', how many times?

___ ___

If 'Yes', reason for admissions: *Please select all that apply*
- ○ Abdominal pain without obstruction or infection
- ○ Query obstruction/subacute obstruction
- ○ Planned further surgery
- ○ Skin/SSI related admission
- ○ Other*

*If 'Other', please specify:

➡ _____
_____
_____
_____

Each 'Other' provided will be entered separately onto the database.

Total number of **inpatient days** (combined for all visits occurring after the patient was discharged from the initial episode for index procedure):
Please answer with the numbers (including 0) of each admission type

Elective admissions - Days: _____   Emergency admissions - Days: _____

➡ If any inpatient admissions, total number of **ITU/HDU days** (combined for all visits occurring after the patient was discharged from the initial episode for index procedure): *Please answer with the numbers (including 0) of each admission type*

Elective admissions - Days: _____   Emergency admissions - Days: _____

ROCSS-EX

Clinical Follow-up Form

Has the patient had any radiological investigations for pain/symptoms at their closure site? This excludes oncological routine follow-up imaging. *Please answer with the numbers (including 0) of each investigation.* *Number of 'Other' only required if 'Other' is specified*

| CT: ___ | USS: ___ | MRI: ___ | Other *(please specify)*: _____ Number of 'Other': ___ |

At any point since their original operation, was the patient diagnosed with an incisional hernia at the site of their stoma closure?   ◯ Yes   ◯ No

⮕ If 'Yes', approximate date of first identification: D D - M M - Y Y Y Y

⮕ If 'Yes', how was this identified? *Tick one*   ◯ CT   ◯ USS   ◯ MRI   ◯ Clinical examination   ◯ Other*

⮕ *If 'Other', please specify: _____

Has the patient been to a hospital outpatient clinic with the primary reason being problems at the stoma site closure/hernia?   ◯ Yes   ◯ No

⮕ If 'Yes', number of clinic visits?   __ __

Has the patient undergone any operations related to their stoma closure? This may include local surgery to the stoma closure site, laparotomies for repair of a stoma site hernia, laparotomies for pathology caused by problems at the stoma closure site e.g. adhesions/small bowel obstruction secondary to incisional hernia.   ◯ Yes   ◯ No

⮕ If 'Yes' please provide the type* and date of all operations performed in the table below.

Operations	
*Types: • Repair of stoma site incisional hernia • Laparotomy & division of adhesions • Laparoscopy & division of adhesions • Bowel resection +/- division of adhesions • Drainage of surgical site infection • Drainage of a seroma • Other (specify)	Date of operation
	D D - M M - Y Y Y Y
	D D - M M - Y Y Y Y
	D D - M M - Y Y Y Y
	D D - M M - Y Y Y Y
	D D - M M - Y Y Y Y
	D D - M M - Y Y Y Y
	D D - M M - Y Y Y Y
	D D - M M - Y Y Y Y
	D D - M M - Y Y Y Y
	D D - M M - Y Y Y Y

Section 2 - FORM COMPLETION DETAILS

Date form completed:	Completed by: *please print name* _____
D D - M M - Y Y Y Y	Signature: _____

Please upload the data collated using this document on to the ROCSS-EX REDCap database.