ROCSS-EX

TELEPHONE FOLLOW-UP FORM (CRF2)

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.

TELEPHONE FOLOW-UP QUESTIONS

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

The following questions should be answered during the telephone consultation

Section 1 - EQ-5D QUALITY OF LIFE QUESTIONNAIRE

These questions are to describe the patient's health **TODAY**.

1. Mobility: *Tick one*
- ◯ I have no problems in walking about
- ◯ I have slight problems in walking about
- ◯ I have moderate problems in walking about
- ◯ I have severe problems in walking about
- ◯ I am confined to bed

2. Self Care: *Tick one*
- ◯ I have no problems washing or dressing myself
- ◯ I have slight problems washing or dressing myself
- ◯ I have moderate problems washing or dressing myself
- ◯ I have severe problems washing or dressing myself
- ◯ I am unable to wash or dress myself

3. Usual Activities (e.g. work, study, housework, family or leisure activities): *Tick one*
- ◯ I have no problems with performing my usual activities
- ◯ I have slight problems with performing my usual activities
- ◯ I have moderate problems with performing my usual activities
- ◯ I have severe problems with performing my usual activities
- ◯ I am unable to perform my usual activities

4. Pain/Discomfort: *Tick one*
- ◯ I have no pain or discomfort
- ◯ I have slight pain or discomfort
- ◯ I have moderate pain or discomfort
- ◯ I have severe pain or discomfort
- ◯ I have extreme pain or discomfort

5. Anxiety/Depression: *Tick one*
- ◯ I am not anxious or depressed
- ◯ I am slightly anxious or depressed
- ◯ I am moderately anxious or depressed
- ◯ I am severely anxious or depressed
- ◯ I am extremely anxious or depressed

6. Health state score: *0-100* ☐☐☐

Section 2 - STOMA SITE PAIN

Pain (relating to stoma site) Visual Analogue Scale score: *0-100* ☐☐☐

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Section 3 - HEALTHCARE VISITS AND INTERACTIONS

Have you seen your GP in a face to face appointment OR telephone appointment because of problems at the site of your original stoma since your operation? ◯ Yes ◯ No

↳ If 'Yes', do you know how many times? ◯ Yes ◯ No

↳ If 'Yes', number of times? _____

↳ If 'No', could you estimate how many times?
◯ Once ◯ 2-5 times ◯ 6-10 times ◯ 11-20 times ◯ More than 20 times

Have you had a hernia truss/support? ◯ Yes ◯ No

Have you received a prescription for medication for your stoma closure site, or any complications linked to your stoma closure site since your operation? ◯ Yes ◯ No

↳ If 'Yes', please provide the type* from the following options, date started and date stopped (or tick if ongoing) in the table below. **Patients may provide medications names - these are to be translated to types when entered in to the ROCSS-EX database.**

**Approximation if exact information not known ***Duration Unit: D = Days, W = Weeks, M= Months, Y= Years

*Type of Medication: • Painkillers • Antibiotics • Laxatives or • Other (specify)	Date started**	Duration**	Duration unit***	Or tick if ongoing
	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			☐

Have you gone to hospital for a planned clinic appointment (NOT as an emergency), regarding your stoma site? ◯ Yes ◯ No

↳ If 'Yes', do you know how many times? ◯ Yes ◯ No

↳ If 'Yes', number of times? _____

↳ If 'No', could you estimate how many times?
◯ Once ◯ 2-5 times ◯ 6-10 times ◯ 11-20 times ◯ More than 20 times

Have you gone to hospital for a planned hospital procedure or stay (NOT as an emergency), regarding your stoma site? ◯ Yes ◯ No

↳ If 'Yes', do you know how many times? ◯ Yes ◯ No

↳ If 'Yes', number of times? _____

↳ If 'No', could you estimate how many times?
◯ Once ◯ 2-5 times ◯ 6-10 times ◯ 11-20 times ◯ More than 20 times

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Have you visited the emergency department at any hospital because of problems at the site of your original stoma, or problems linked to your stoma site since your operation? ◯ Yes ◯ No

↳ If 'Yes', do you know how many times? ◯ Yes ◯ No

↳ If 'Yes', number of times? _____

↳ If 'No', could you estimate how many times?
◯ Once ◯ 2-5 times ◯ 6-10 times ◯ 11-20 times ◯ More than 20 times

Do you think that you have or have had a hernia at the site of your stoma closure? ◯ Yes ◯ No ◯ Don't know

↳ If 'Yes' date first noticed (if exact date unknown please provide approximate date): D D - M M - Y Y Y Y

Section 4 - HerQles QUESTIONNAIRE

For the following statements please circle the number that is most appropriate for your patient.

	Strongly Disagree	Moderately Disagree	Slightly Disagree	Slightly Agree	Moderately Agree	Strongly Agree
1. My **abdominal wall** has a huge impact on my health	1	2	3	4	5	6
2. My **abdominal wall** causes me physical pain	1	2	3	4	5	6
3. My **abdominal wall** interferes when I perform strenuous activities	1	2	3	4	5	6
4. My **abdominal wall** interferes when perform moderate activities such as bending down	1	2	3	4	5	6
5. My **abdominal wall** interferes when I walk or climb stairs	1	2	3	4	5	6
6. My **abdominal wall** interferes when I dress myself, take showers and cook	1	2	3	4	5	6
7. My **abdominal wall** interferes with my sexual activity	1	2	3	4	5	6
8. I often stay home because of my **abdominal wall**	1	2	3	4	5	6
9. I accomplish less at home because of my **abdominal wall**	1	2	3	4	5	6
10. I accomplish less at work because of my **abdominal wall**	1	2	3	4	5	6
11. My **abdominal wall** affects how I feel every day	1	2	3	4	5	6
12. I often feel blue because of my **abdominal wall**	1	2	3	4	5	6

Section 5 - TREATMENT ALLOCATION

Has the patient expressed a wish to be informed of the treatment they received when their stoma was reversed? *Tick one* ◯ Yes ◯ No

↳ If 'Yes', please provide their preferred contact details, either postal address or email address:

Postal address:	Email address:
_____	_____
_____	_____
_____	_____

Section 6 - COMPLETION DETAILS

Date form completed:
D D - M M - Y Y Y Y

Completed by: *please print name* _____

Signature: _____

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