ROCSS-EX FREQUENTLY ASKED QUESTIONS

GENERAL

What is ROCSS-EX?

- **ROCSS-EX** is a study looking at extended follow-up of the **ROCSS** trial, 5-8 years after randomisation into the study.
- It uses information from routinely recorded data in a participant's medical records and a telephone interview.
- **ROCSS-EX** has been introduced as an amendment to the existing **ROCSS** trial in substantial amendment number 7 (2nd December 2020).

Where and when will ROCSS-EX run?

Where: All sites that participated in the original **ROCSS** trial are invited to take part in **ROCSS-EX**.

When: The study is now open so once local and central approval is granted, collaborators can begin to collect data. This is envisaged to take approximately a month and must be completed by July 2021.

Who will be involved in ROCSS-EX?

As with the original trial, trainees are playing the lead role in the delivery of the extended follow-up.

Person/Team	Role and Expectations
Principle Investigator at site	• Identify Trainee Investigators • Provide oversight and overall responsibility at the site • Support trainees in beginning the trial follow-up • Oversee data collection and entry ensuring time frames are being met
Trainee Investigator(s) at site	• Use list of existing **ROCSS** trial participants contained in the local **ROCSS** Investigator Site File (ISF) to identify participants • Use local records to identify deceased participants in order to not send them correspondence • Complete clinical follow-up using notes/electronic health records for all participants who consented to long term follow-up in the original study: ▪ For living participants, complete the data entry from notes/electronic resources from surgery to present ▪ For participants who have died, complete the data entry from notes/electronic resources from surgery to date of death *Also see How do I find the list of ROCSS participants for follow up* • Contact surviving **ROCSS** participants (posting of REC approved letter and PIS, and subsequently by telephone), complete telephone follow-up consultation within agreed time frame • Enter follow-up data on to **ROCSS-EX** REDCap based by July 2021 – paper CRF will be provided to use for data collection • Address any data queries raised by the **ROCSS-EX** Trial Team • Highlight to PI (and **ROCSS-EX** Trial Team where applicable) any issues regarding data entry/collection • *There are no set limits on the number of trainees that can be involved but we recommend 1 trainee investigator per 10 participants (please also see the publication policy).*
R&D Departments at site	• Review and approval of substantial amendment
Research Nurses at site but may be undertaken by PI, Trainees or by admin support outside of R&D (e.g. medical sectaries)	• Supply Trainee Investigators with the list of participants based on the **ROCSS** Patient Identification Log contained in the **ROCSS** ISF • Assist with update to **ROCSS** ISF, including site personnel records (delegation log etc.) • Supply equipment i.e. envelopes, stamps for posting documents to each patient prior to telephone contact *If capacity and/or the desire for involvement, RN involvement to assist Trainee Investigators in completion of follow-up and data collection and other **ROCSS-EX** activities is welcomed.*

SET-UP AT SITES

What is need to get started with ROCSS-EX?

1. Local approval of substantial amendment number 7 (02-Dec-2020) must be in place – it will be implemented on 18-Feb-21 after the 35 day review period is completed (if confirmation of capability & capacity is not received prior to this date, or more time to review is not requested).
2. Relevant documents for anyone involved in the study must be provided to the Trial Office:
    a. **ROCSS-EX** Delegation Log; available for download and will need to be completed, signed and returned to BCTU.
    b. CV (signed & date, ideally short research); you can find a useful CV template here .
    c. GCP; both full *and* refresher training is available online through NIHR Learn. If you have completed GCP before, you only need to do the refresher training.
    Please note: CV & GCP should be within 36 months or in accordance with local policies and requirements.
3. Completion of **ROCSS-EX** training; this may be delivered directly by the Trial Team, the local PI or online - please document the completion of training using the ROCSS-EX Electronic Training Log.
4. A Trust (or equivalent) email address is required - personal email addresses can be used for post-data collection correspondence, such as sharing of the publication, or maintaining contact after you've left the trust, but not for correspondence during the data collection period.

How do I know ROCSS-EX has started at my site?

Once the Trial Office has received local approval and the personnel documentation (including training), sites will be informed by email by the Trial Office that **ROCSS-EX** activities can begin and granted access to the **ROCSS-EX** database.

Are there any other R&D considerations?

ROCSS-EX involves contact with and follow-up of existing participants and so the activities are not viewed as accruals by the CRN; additional resources over and above those already received will not be provided and there are no research costs that will be provided to participating organisations. However, the CRN would see any site follow-up activity favourably. This does mean that there are no targets or RAG statues that site will be accountable for and the Trial Office will contact the local PI and Trainee Investigators to facilitate the day-to-day delivery of the study.

ROCSS-EX DELIVERY

How do I find the list of ROCSS participants for follow up?

The Participant Identification Log in the **ROCSS** Investigator Site File (ISF) lists all the patients recruited to the trial at that site. It includes trial number, hospital number, name, date of randomisation and date of surgery. If there are difficulties locating or accessing the ISF, please consult your local R&D; it may have be placed in interim storage given the time since the completion of the original **ROCSS** study, and/or R&D may have an electronic participant record.

Not all **ROCSS** participants will be included in **ROCSS-EX**; only those that actually had their stoma reversed and did not withdrawn from the trial during the original study period.

Once access to the **ROCSS-EX** database is in place, site staff will be able to view the refined participant list. This list will only contain patients who had there stoma reversed and who did not previously withdraw from participation; these patients will be absent from your site list in REDCap. It does include participants for who it was not possible to re-consent to long term follow-up during the during the original trial period. However, for this group of patients, clinical follow-up data is disabled until their agreement to participate in ROCSS-EX is established. Therefore it not possible for you to enter any data for any patient unless the necessary consent is in place.

The "Patient Record" form within the database contains the same information as the paper Participant Identification Log; trial number, hospital number, name, date of randomisation and date of surgery. This allows for crosschecking of the information.

The first step is to look up participants on the local systems to prepare the mailing list, establishing if they are still alive and have present.

Do participants need to be re-consented?

During the original ROCSS trial participants were re-consented to long-term follow-up using routinely recorded data. The existing ROCSS consent does include the agreement of participants to be contacted by post and telephone but in the context of the original study. An "opt out" approach, approved by the Research Ethic Committee (REC), has been applied to the continued participation of ROCSS participants:

1. Participants are sent the **ROCSS-EX** Participant Letter and **ROCSS-EX** Participant Information Sheet (PIS) which explains:
    - the nature and purpose of the follow-up
    - the local team will contact them by telephone at least two weeks later to undertake the follow-up, or arrange a time that is convenient for them to complete it
    - instructions on how to opt out of the follow-up by telephone; telling the local team member when they call, or contacting the local team beforehand by either post, telephone or email, or the Trial Office by email
2. If no "opt out" indication is received prior to the data/time of the telephone consultation specified in the letter, the participants can be contacted by telephone.
3. Establish verbal agreement to participate in **ROCSS-EX**. The participants continuing consent to take part in the study must be documented in their medical records, either by adding a note to their electronic health record, or to their paper records.
   E.g. "ROCSS-EX PIS v2.0 (12-Jan-21) and ROCSS-EX Participant Letter v2.0 (12-Jan-21) sent on 01-Mar-21. Contacted by telephone 15-Mar-21; patient agreed to continued participation in ROCSS and ROCSS-EX telephone consultation undertaken."

The ROCSS-EX database requires confirmation of agreement/consent before any data can be entered.

What if a patient has moved out of area?

If participants are no longer under the care of the site where they were randomised please tell the Trial Office. If and what data collection can be undertaken will depend on the individual circumstances:

- If under another **ROCSS** site, the Trial Office will add them to the Participant List at the "new" site and the local team there are asked to complete the telephone follow-up along with providing clinical follow-up data.
- If under a non-**ROCSS** site, attempt to contact the participant via their new hospital if possible in order to complete the telephone consultation – the primary outcome measure is the HerQLes quality of life questionnaire so every effort to collect this information is encouraged. If it is feasible to obtain data relating to the clinical follow-up from the participant's new hospital, this is also welcomed.

In the meantime, as much clinical follow-up as possible should be entered using the medical records available at the site, as well as notifying the Trial Office.

How is the data collected?

Trial data will be entered by the local research team directly into the REDCap-based **ROCSS-EX** database. Access will be granted to local PIs and members of the local research team assigned the "Completion of electronic CRFs/data entry including data query resolution" on the log. Paper versions of the eCRF can be used as worksheets to collect the data before entering it into the **ROCSS-EX** database. Once they are no longer needed, please dispose of them in confidential waste, as they do not need to be sent to the Trial Office.

The **ROCSS-EX** database consists of 4 forms:

- **Patient Record** – summary of participant details along with information on participant contact and agreement to take part, which in turn determines if/when data can be entered in to CRF1 and CRF2.

- **CRF1 (Clinical Follow-up)** – data covering date of surgery to present (or death) from review of medical records.
- **CRF2 (Telephone Follow-up)** – data from telephone consultation with participant.
- **PI sign-off**

The **ROCSS-EX** REDCap database can be accessed securely from any computer with internet access.

To support remote working, off-site access to medical records (e.g. by a remote desktop) may be available depending on the trust – please discuss with the local PI and contact the Trial Office if there is anything we can do to support such access being granted.

Please note – the **ROCSS-EX** database will go live w/c 8th February 2021.

How long does the follow-up take?

We expect it will take an hour on average to complete the follow-up for an individual participant. This includes initial review, sending the **ROCSS-EX** documents, collation of data from the medical records, telephone consultation, data entry into the database and resolution of data queries. Many activities may be grouped, such as preparing and posting letters to a batch of participants, scheduling several 10-15 minute telephone consultations for a single afternoon etc.

What support and guidance is available?

ROCSS-EX Telephone Script provides assistance in completing telephone consultations.

The **ROCSS-EX** Database User Guide provides information on how to navigate and use the database.

Regional Trainee Leads – each site has a nominated Regional Trainee Lead who will be able to support Trainees Investigates and other staff at sites with any questions (see below).

Region	NORTH	CENTRAL	SOUTH
Lead	**Zoe Gates** zgates83@gmail.com	**Alasdair Ball** alasdair.ball@googlemail.com	**Ellen Jerome** ellen.jerome1@nhs.net
Sites	Chesterfield Royal Hospital Doncaster Royal Infirmary Macclesfield District General Hospital Queen's Medical Centre Raigmore Hospital Royal Albert Edward Infirmary Royal Stoke University Hospital Tameside General Hospital University Hospital Of North Tees Wythenshawe Hospital York Hospital	Birmingham Heartlands Hospital King's Mill Hospital Leicester General Hospital James Paget University Hospital Manor Hospital New Cross Hospital Norfolk & Norwich University Hospital Pilgrim Hospital Queen Elizabeth Hospital Birmingham Sandwell General Hospital University Hospital Coventry Worcestershire Royal Hospital	Bristol Royal Infirmary Broomfield Hospital Dorset County Hospital Queen Elizabeth The Queen Mother Hospital Royal United Hospital Bath Salisbury District Hospital St Mark's Hospital St Peter's Hospital St Richard's Hospital Yeovil District Hospital

The Trial Office will also provide help and support; ROCSS@trials.bham.ac.uk.

PUBLICATION POLICY

As with **ROCSS**, there will be a corporate authorship policy for the **ROCSS-EX** results publication, and all collaborators with be PubMed citable authors. Local PIs will form part of the **ROCSS-EX** Collaborative. As a guide for other site staff (Trainee Investigators, Research Nurses etc.), the completion of follow-up for 10 participants will qualify them to become part of the **ROCSS-EX** Collaborative. However, individual circumstances for a given sites will be taken into consideration, such as number of participants recruitment, number of participants included in **ROCSS-EX** and participants decisions, favouring inclusion in the Collaborative.