The ROCSS (Reinforcement Of Closure of Stoma Site) study was developed by the West Midlands Research Collaborative (WMRC) and the University of Birmingham Clinical Trials Unit (BCTU).

The study is lead by Mr Aneel Bhangu and Miss Kay Futaba under Professor Dion Morton, as Chief Investigator.

The lead local researcher for a multi-centre study is the local Principal Investigator.

In the ROCSS trial the role of Local Principal Investigator carries certain responsibilities:

- Day-to-day responsibility for the conduct of the research
- Responsible for recruitment into the study at site
- For ensuring the Research Governance requirements for the centre and the study are met
- To ensure the agreed protocol is followed
- Helping care professionals ensure participants receive appropriate care while involved in the research
- The integrity of records and ensuring they are kept confidential
- Reporting adverse reactions

All sites require Trust approval from their Local R&D department before the study can commence at site.

- No patients can be approached for consent to join the trial until this is in place.
- This process is called Site Specific Assessment (SSA). This is gained by the submission of the Site Specific Information (SSI) Form to NRES.

The ROCSS Trial Office can assist in the approval process if this form is completed and returned to the ROCSS study office. The Trial Office will complete the necessary paperwork and return to the PI for signature and submission. Approval will require liaison between the PI and the Trust R&D Office to gain approval, but the Trial Office will help as much as possible.

- The local R&D office will assess whether the local PI has the necessary training and experience to undertake the study.
- The local R&D office will require indication of relevant recent research experience.
- The local R&D office needs to know who the other investigators are who will have a significant research role (e.g. clinicians and research nurses).
- All investigators should comply with the requirements of the Research Governance Framework for Health and Social Care. This document can be found on the Department of Health website: www.dh.gov.uk.
- The local R&D office will also wish to be reassured that the PI has time to undertake the proposed project and fulfil their responsibilities.
- The local R&D office will want reassurance that all persons taking consent locally are appropriately trained for the task, by being aware of the nature of that process and familiar with “best practice” and that these persons should have sufficient time and expertise to answer all questions that might be raised by ROCSS participants.
The ROCSS Trial

Site Registration Form

For all centres wishing to participate in the ROCSS trial:
Please complete all sections below and return to the ROCSS Trial Office.

PRINCIPAL INVESTIGATOR

Name: __________________________________________________________
Position: _______________________________________________________
Qualifications: __________________________________________________
Department: ____________________________________________________
Hospital: _______________________________________________________
Address: _______________________________________________________
Telephone: __________________ Fax: _____________________________
Email: _________________________________________________________

1. Has the PI performed at least 20 stoma closures?
___________________________________________________________________________

2. Location for research: (To include locations for consent, CT, surgery and follow-up)

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<thead>
<tr>
<th>Location</th>
<th>Research activity</th>
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3. Number of participants expected to be recruited:
   a. In the first year? __________________________
   b. For the duration of the study: __________________________

4. Who will be responsible for obtaining consent at site?
   (Anyone taking consent should be GCP trained; a copy of the certificate should be held at site
   and will be requested by R&D and the ROCSS trial office).
_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________
The ROCSS Trial

5. Is there an independent contact point where potential participants can seek general advice about participation in research?

_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________

6. Is there a contact point where potential participants can receive further information about ROCSS?

_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________

7. What local arrangements do you plan to make for participants who do not adequately understand English?
   a. Use PALS interpreter
   b. Unlikely to be required
   c. Other

8. Name of Clinical Director (or other person responsible for authorisation of research in the department).

_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________

9. Is there a clinical trials office or department that BCTU should correspond with to help in the set up of your site? If so, could you please supply a contact name and contact details?

_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________

Members of the research team

Additional participating consultant **surgeon** (other than PI):
Name
Telephone
Fax
E-mail
Approx. how much time will be spent working on the trial?
The ROCSS Trial

Participating **surgical registrars:**
Name __________________________________________
Telephone _______________________________________
Fax _____________________________________________
E-mail __________________________________________
Approx. how much time will be spent working on the trial? ________________

Name __________________________________________
Telephone _______________________________________
Fax _____________________________________________
E-mail __________________________________________
Approx. how much time will be spent working on the trial? ________________

Participating **radiologist:**
Name __________________________________________
Telephone _______________________________________
Fax _____________________________________________
E-mail __________________________________________
Approx. how much time will be spent working on the trial? ________________

Participating **research nurse:**
Name __________________________________________
Telephone _______________________________________
Fax _____________________________________________
E-mail __________________________________________
Approx. how much time will be spent working on the trial? ________________

Thank you for completing the site registration form.
Please return to the ROCSS Trial Office by e-mail, post or fax:

ROCSS Trial Office
FREEPOST RRKR-JUZR-HZHG, Birmingham Clinical Trials Unit, School of Cancer Sciences, University of Birmingham, Edgbaston, Birmingham, B15 2TT.

Trial Coordinator: Dr Laura Magill
E-mail: e.l.magill@bham.ac.uk; Fax: 0121 415 8871

Please remember to include:
- Signed and dated CVs for all lead researchers
- GCP certificates when available
- Local Trust headed paper (electronic version)