

ROCSS-EX

ROCSS-EX is an extension of follow-up of the **ROCSS** trial. It will involve a single time point at 5-8 years (depending on when the individual participant was randomised) from routinely record data participant and telephone interview. As with the original trial, trainees will be play a key role in the delivery of the extended follow-up.

Roles and Responsibilities of ROCSS-EX Site Staff

Person/Team	Role and Expectations
Principle Investigator at site	<ul style="list-style-type: none">Identify Trainee InvestigatorsProvide oversight and overall responsibility at the siteSupport trainees in beginning the trial follow-upOversee data collection and entry ensuring time frames are being met
Trainee Investigator(s) at site	<ul style="list-style-type: none">Use list of existing ROCSS trial participants contained in the local ROCSS Investigator Site File (ISF) to identify participants that are deceasedComplete clinical follow-up using notes/electronic health records for all participants:<ul style="list-style-type: none">For living participants, complete the data entry from notes/electronic resources from surgery to presentFor participants who have died, complete the data entry from notes/electronic resources from surgery to date of deathContact surviving ROCSS participants (posting of REC approved letter and PIS, and subsequently by telephone), complete telephone follow-up consultation within agreed time frameEnter follow-up data on to ROCSS-EX REDCap based database within agreed time frame – paper CRF will be provided to aid data collationAddress any data queries raised by the ROCSS-EX Trial TeamHighlight to PI (and ROCSS-EX Trial Team where applicable) any issues regarding data entry/collection
R & D Departments at site	<ul style="list-style-type: none">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 secretaries)	<ul style="list-style-type: none">Supply Trainees Investigators with the list of participants based on the ROCSS Patient Identification Log contain in the ROCSS ISFAssist 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 <p><i>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.</i></p>

ROCSS-EX involves contact with and follow-up of existing participants – the activities are not viewed as accruals by the CRN and additional resources over and above those already received will not be provided. **However, the CRN would see any site follow-up activity favourably.**

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ROCSS-EX Regional Trainee Leads

Each ROCSS site has been assigned to **ROCSS-EX** Trainee Lead who are part of the central **ROCSS-EX** Trial team and will:

- Keep regular contact with designated sites
- Be point of contact for PI/Trainee Investigators/Research Nurses for questions related to **ROCSS-EX**
- Communicate developments between Sites and **ROCSS-EX** Trial Team

Region & Lead	Sites
NORTH	Chesterfield Royal Hospital
Zoe Gates	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

Region & Lead	Sites
CENTRAL	Birmingham Heartlands Hospital
Alasdair Ball	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

Region & Lead	Sites
SOUTH	Bristol Royal Infirmary
Ellen Jerome	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