Set Up

Will this be a singular IRAS/REC submission to cover the four domains and require one study-wise review?

There will be one IRAS submission and ID for CoReCCT, Awake Prone and RELEASE. PROTECT Airways and UK NAVA have been submitted as an amendment under this CoReCCT IRAS ID. Sites can review CoReCCT as a whole and select which studies they wish to partake in, as such, requiring only one review.

As a site, can we pick which of the four CoReCCT domains we participate in, or do we have to participate in all four?

It is up to individual sites to decide how many of the domains to take part in. You can start with one or two and add more at a later date.

Will the contract only specify which domains the Trust is taking part in?

Yes, only the domains you are partaking in will be listed in the contract. If you wish to add another domain at a later date, we will file a variation to contract.

Does each domain have to start at the same time?

No, we are flexible as to starting times for each domain.

How is this different to a platform trial?

Whilst there is similar functionality to platform trials, there are some notable differences. Each of the four domains collaborate under the 'CoReCCT' banner to achieve consistency and efficiency for NHS staff, patients, the funder and the coordinating team wherever possible. Yet, where needed, the domains also benefit from having an independence that is not achievable in platform design trials.

Who can act as PI?
We take a pragmatic approach to the PI role. Any healthcare professional that is suitably trained and experienced may undertake the role of PI. Whilst experienced consultants are welcome to act as PIs, staff other than consultants can act in this role, provided the Trust feels there is sufficient experience in the team and any less experienced PIs have support and mentorship, as needed.

Staff including speciality grade doctors, long term clinical fellows, physiotherapists, senior outreach and ITU nurses and AHPs could be considered locally for the PI role, where appropriate.

Will there be one overall PI for all domains, or can there be different PIs on each domain?
We are keen to be as flexible as we can. You will be free to decide whether you have one PI overseeing each CoReCCT domain at your site, or if you wish to have multiple PIs varying by domain.

Are you supporting the Associate PI scheme for these studies?
Yes, for each trial. You can have more than one API per study at any one time.

Can there be 2 or more simultaneous Associate PI Trainees who are in the midst of their 6-month tenure, at the same site, at the same time?
Generally, most PIs will only be mentoring one Associate PI Trainee at a time. However, if the local PI is happy to mentor more than one Associate PI Trainee at a time then we will allow this. We are led by the capacity of the local PI. Please email associatepischeme@nihr.ac.uk to inform us if there are going to be two Associate PI applications for one site. https://www.nihr.ac.uk/documents/associate-pi-scheme-faqs/11698

What training will sites receive?

We will provide training to cover the shared principles of CoReCCT in addition to domain specific training for the studies you wish to participate in. Site initiation training will be provided, in addition to online training resources. Each trial will also provide robust intervention training packages, as required, to support delivery by multi-disciplinary teams.

How does delegation work?
To keep things simple, we will record your delegated responsibilities for each domain that you work on. This should help to avoid any confusion where there is varying team cross over across the domains.

Will we have an electronic investigator site file?
Yes, we will host our template ISF on our study webpages. You will be able to download this document set to form your local ISF. You can choose to maintain this electronically at your site or via paper folder, if preferred. Any amendments and document updates will be distributed electronically.

Recruitment

How do we randomise?
There will be a trial database for CoReCCT. When you are ready to randomise, you will go here to recruit the patient to the relevant domain. You will then go back here to recruit this same patient to a subsequent domain, as appropriate.

Will participants receive multiple trial numbers?
No. If a participant is recruited to multiple trials, a unique trial number will be generated for the first trial, and this will be linked to later trial randomisations.

How do we co-enrol where deferred consent is obtained? (PROTECT Airways & UK NAVA only)
If a participant has previously been recruited to one CoReCCT domain but is then recruited to PROTECT Airways or UK NAVA via deferred consent, it is not ethical for us to immediately link their data on the CoReCCT database. Instead, a temporary ID will initially be allocated. Once a participant consent or consultee agreement is in place, their record will be linked to the existing trial number and shared data collection will resume. If for any reason consultee or participant consent is never obtained, the participant's database records will remain unlinked.

How do accruals work?
Each domain will have its own CPMS ID and accruals will be logged for every participant recruited to each domain. This means that if you co-enrol a patient to multiple CoReCCT domains, you will receive an accrual for each individual recruitment. WCTU will submit accruals data via CPMS on behalf of trial sites.

Will you co-enrol with external trials too?
Yes, we aim to promote co-enrolment with interventional trials outside of CoReCCT. We will list approved trials on our website. Please do let us know if there are any trials to prioritise for review at your site. Co-enrolment will be permitted with non-interventional observational studies without the need for a co-enrolment agreement.

How do you plan to take consent? Will there be a separate approach and PIS for each study. Is there a risk of overwhelming patients?
Each domain will take consent and use its own PILs. The consent form used over the 4 trials is the same except for some optional items relating to SWAT and bloods for AP and RELEASE respectively.

Data

How will we manage in hospital data completion?
The majority of the data collected is consistent across the CoReCCT domains with a small quantity of trial specific data collected. This means that if a participant is recruited to multiple trials, you may only need to enter this core data via our shared database once and the format will be consistent.

How does participant follow-up data work?
WCTU will manage the collection of participant follow-up data. Participants will complete questionnaires at the 2- and 6-month follow-up timepoints. If they take part in multiple domains, this will take place based on their most recent randomisation date. There will be just one questionnaire to complete at these timepoints regardless of how many domains they participate in reducing burden greatly.

How does safety reporting work?
Where a participant is recruited to multiple trials, any reportable SAEs will be entered once on the database with a causality assessment completed for each trial intervention.