

1ST CLASS DELIVERY

Newsletter Issue 3, March 2021



Site opening & Recruitment



Site Name/Code	Date Opened	Randomised Participants
Sunderland Royal Hospital/ 04	09/12/2020	40
Poole Hospital/ 17	18/12/2020	7
Queen Elizabeth Hospital, Gateshead/ 14	22/01/2021	15
Medway Maritime Hospital/ 15	12/02/2021	17
Total (as of 26/03/2021):		79

“How to COPE” Drop in sessions

You are invited to drop in to chat to Professor Andrew Weeks/ central COPE team/ other COPE sites



16:00 on Wednesdays

Please contact us if you have not received the calendar invite

This is an opportunity every week for members of your team to directly talk to the team & other sites to gain advice on “How to COPE”. These sessions have proven very popular with open sites and sites in set up & is a great way to build upon the COPE community. Frequently asked questions are added to the study website weekly.



Meet the recruiting sites



Sunderland Royal Hospital



Medway Maritime Hospital



Poole Hospital



Queen Elizabeth Hospital, Gateshead
Image taken pre-covid

Tips from sites

Train as many recruiting doctors in COPE as possible and add to the delegation log

Ensure shift handover processes are efficient, including use of COPE magnets on whiteboards

Consult study website frequently asked questions (FAQs) section as there is an extensive list of questions previously asked by sites

Initial de-briefs with women following recruitment, prior to formal consent discussion to make them aware that someone will talk to them about the study. Patient Information Sheet and Consent Form (PISC) can be provided at this time

Provide women with the phone number of the research midwives so that they recognise the phone number for follow-up calls

Website Resources

Useful Resources, including:

- Power Point Training Presentations & Videos
- Good Clinical Practice (GCP) Training Requirements
- Frequently Asked Questions (FAQs)
- Recruitment Updates
- Embedded Study Reference Guide

Essential documents, including:

- Study Protocol
- Pharmacy Documents
- Embedded Study Documents



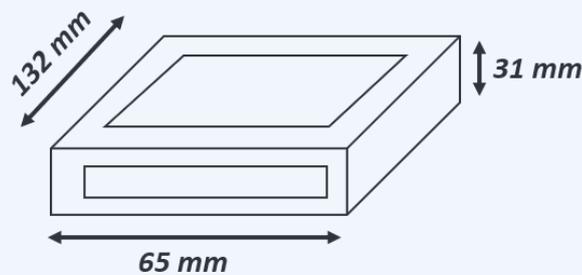
Please contact us for site staff login details

Kit deliveries

There will be 2 kit campaigns - where possible we aim to have 1 bulk delivery in each of these campaigns to cover sites for each campaign period.

Campaign 1 expiry is **Dec 2022**. Depending on recruitment rate, you will be re-supplied with more kits as appropriate.

Average sites (recruiting 4-6 per month) have been provided with 60 kits for campaign 1. This is largely dependent on pharmacy capacity – please discuss with your pharmacy teams and let us know how many kits you would like in your first delivery. We can then allocate these to you prior to ordering and completion of site set up.



Please ensure that as soon as the kits are received & refrigerated that the “Stop” button is pressed on the Tempsen USB temperature recorder, otherwise the temperature reading will rise prior to downloading the data.

Secure transfer of documents to Liverpool Clinical Trials Centre (LCTC)

Emails from an @nhs.net account do not automatically send securely to cope@liverpool.ac.uk. Instead, to email documents securely, send from an email address ending in @nhs.net and...

- At the start of the email subject line add **[SECURE]** as this will encrypt your email and attachment(s). [SECURE] must be written in capital letters and must be surrounded by square brackets.
- **Do not** send consent forms in the same email as any other COPE case report form as only specific individuals within the COPE team should be able to link patient identifiers within consent forms to the patient's medical data.



Embedded Study

- **Part A** – Audio-recordings (selected sites only)
- **Part B** – *Questionnaires (All sites)
- **Part C** – Interviews (All sites)
- **Part D** – Focus groups &/or PI interviews (selected sites only)

** If consent has been received for completion please ensure these are available for completion on site. Questionnaires will need to be posted home if not completed on site.*

Documenting consent for the Embedded Study:

- To every consent discussion, remember to take an embedded study birth partner consent form & 2 copies of the applicable embedded study questionnaire as well as the usual PISC for the woman.
- **Women:** record this on the same consent form as the main COPE study
- **Birth partners:** record this on the “Embedded Study Birth Partner Consent Form”
- The embedded study consent items are independent of each other; therefore women and their birth partners can consent to as many or as little of the items as they wish.

Where to return the documents to?

- The “Embedded Study Birth Partner Consent Form” should be securely emailed (in the same way as the woman’s consent form) to cope@liverpool.ac.uk.
- The embedded study questionnaires (different to the main study 24hr questionnaire) should be posted to: **Kerry Woolfall, Block B, Room B112, 1st Floor, Waterhouse Building, Liverpool, L69 3GL**

COPE Eligibility

All sites are provided with COPE eligibility magnets in their site file packages. Recruiting sites have found these useful for use on whiteboards as a way to focus recruitment processes, especially during shift handovers.

Where possible, all women that have a PPH will be assessed for their eligibility at the time of the PPH. However, if it is known before a PPH that the patient is ineligible, then the COPE ineligible magnet can be used to inform the wider team of this.



Updates & Notices

PISCs: Localised PISCs (pdf) will be provided to each site during set up. These pdf versions must be used to prevent the PISC format altering during email transfer. If your site requires PISCs to be localised by site, please ensure that they are reviewed & approved by the COPE Trial Coordinator prior to site opening to recruitment & use.

Amendments: The Protocol and all PISCs are currently being updated, along with the IMP Dossier – to include additional kit stability data outside of 2-8°C.

Quarterly collection of PPH data: Recruiting sites will be contacted to provide data on the no. of PPH cases each quarter. This will help us to further understand the screening data collected.

THANK YOU!

To all sites for your continued support & all of your hard work setting up COPE.

We'd love to hear your feedback on our newsletters -

Please send any comments/suggestions for future features to cope@liverpool.ac.uk

