**Frequently Asked questions**

1. **Do we need to have approval by 17th March?**

The study window runs from the 17th March- 17th May, meaning you can start to screen eligible participants and recruit as late at the 10th May if you wish, as you would have to finish all the 24 hour data collection by 23:59 of the 17th of May.

1. **When does the study close?**

Follow up occurs at 6 weeks +/-3 days, therefore the study will close on 1st July 2025. Data capture (REDCAP) will close 4 weeks after this (29th July 2025)

1. **What do we do about recruiting? We won’t be able to recruit all patients for CRF 2, we won’t have the staffing for that!**

We aim for all patients to have CRF1s completed at the time of their delivery. In some this may be done afterwards. In some patients who have deliveries over the weekend – it might be difficult to consent them within 24 hours. We expect this. You can only do what you can do, but don’t let this stop you from participating.

1. **Who should do the consenting/following up?**

Any member on the delegation log, delegated that role by local the PI can do the consenting and follow up. In some cases, it may be that the person who does the anaesthetic care for the case, also does the consent beforehand (for example, at the pre-op visit before an elective caesarean deliveries), but it is not appropriate for the person who was clinically responsible for the case, and did the anaesthetic, to then follow up for feedback at 24 hours. The CRF1 (the intraoperative data collection tool) can be done by anyone – either the clinician responsible for the anaesthetic of the case, or a member of the study team. They don’t need to have GCP or be on the delegation log.

1. **Do we send on the consent forms to you?**

No, consent forms or paper CRFs should be sent to the central study team. Only anonymised data via Redcap.

1. **How do we collate telephone numbers for CRF3**

For the pilot we asked patients to provide their telephone numbers on CRF2 so we could find it easily when it came to collect for CRF3. This is best decided by each site as to what fits their working pattern. However, sites might it useful to keep a telephone number log in their secure file, or to use EHR, or to add it to the screening log.

1. **What does ‘direct care team’ mean?**

The anaesthetist responsible for the case may consent and discuss the study with the patient. Indeed, for non-urgent and elective surgery, where this process occurs before the delivery, this may be the most appropriate person. However, it is not suitable that the person giving the anaesthetic and clinically responsible for the case then subsequently fills in CRF2 with the patient which asks for feedback, the patient may feel that they cannot speak freely. This is why the protocol suggest that the ‘direct care team’ does not do the post operative 24-hour data collection.

1. **When do we approach for consent?**

For non-urgent and elective surgery, it may be possible for the patients to review the PIS and consent to the study before the delivery. For example, at the preoperative visit before an elective procedure, or on admission to labour ward, or in a preassessment clinic. Postoperatively, we would strongly recommend against approaching patients just after they have received an anaesthetic, especially in cases of GA, IV systemic opioids or other analgesia. Local research teams must exercise clinical judgement as to when a patient is ready to receive and comprehend study information and provide informed consent, whilst being mindful that CRF2 should be completed within 30 hours of delivery. Often completion of CRF2 and consent is done in the same visit, minimising visits.

1. **How will we reach the Saturday and overnight patients?**

It may not always be possible for sites to achieve 100% CRF2 completion. Several patients may ‘time out’ and this should be recorded on the site log. The window for CRF2 completion is 24 hours (+/- 6 hours) and thus as long as the patient is consented and CRF2 done within 30 hours, this is legitimate. Where possible, a member of the research team would be available at the weekend, but this is not always feasible for many sites.

1. **Can we complete CRF1 retrospectively?**

Yes, it may not always be possible for the CRF1 to be done contemporaneously at the same time as the clinical case. It is perfectly reasonable for the study team to fill these in retrospectively. For example, if a night doctor has left already, and there is a case from overnight, it would be reasonable for fill in the CRF1 for them. It is suggested that you contact the clinician responsible for the case, to ensure there were any incidences of intraoperative pain that are not reflected in the clinical record. Where possible, CRF1 should be completed as close to the case time as you are able, to reduce bias.

1. **How do we get our redcap site numbers?**

Redcap site numbers will be autogenerated by Redcap and will include a site-specific prefix. This will be sent out following local capacity and capability review.

1. **Can we have more than 2 logins for redcap?**

In keeping with best information governance practices, we will provide two redcap logins for sites. The PI, and another. It is left to the discretion of the local PI as to who has these logins. If further logins are required the PI will be required to email. We will not accept an email from anyone else.

1. **Can we start consenting from day 1?**

CRF1 data collection, screening for eligibility, and consenting starts from 00:01 on the day that you choose to start the study. This can be any day between the 17th March and 17th May 2025. We wouldn’t expect any CRF2 data until at least 18 hours after this, as the window for this data is 24 hours (+/- 6 hours). The six-week data collection is 6 weeks after your operative data collection window and will likely fall later in the summer.

1. **When does the ‘timer’ start?**

The CRF2 should be collected within 24 hours (+/- 6 hours) of delivery.

1. **How do the accruals work? Are there accruals for CRF1?**

Accruals are based on the number of patients enrolled, consented and completed CRF2.

1. **Do you need GCP to be on the delegation log?**

Yes, we recommend all those on the delegation log you have GCP. This is because only those who are on the delegation log can consent, enrol, and collect CRF2 and 3 data from the patients. The non-consenting part of the study (CRF1) does not require GCP, or to be on the delegation log, or to be part of the ‘study team’.

1. **Who can be a PI? How many PIs can we have?**

Any appropriately qualified person who has GCP and an appropriate contract with your trust can be PI. More than one Co-PI is acceptable as long as approved by your local R&D.

1. **Do we need consent for CRF1?**

No, CRF1 is non-consenting as it is routinely collected audit data. Data from CRF1s for patients who then do not go on to consent for the study can and should still be sent to the study team via redcap.

1. **What’s this Qualitative interview study**

In selected patients, they will be invited to be part of a separate qualitative study (different ethical approval, IRAS form and consent) we will be sending out details of this for interested sites soon.