Study-Specific SOP

A randomised feasibility study of real-time intracavity ECG and thoracic ultrasound for central venous catheter tip confirmation in critical care

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise.

If you are reading this in printed form check that the version number and date below is the most recent one.

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Author:	Andrew Chamberlain
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Approved by:	Name/Position:	Rupert Jackson, Research Programme Manager
	Date:	14 MAY 2026
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	18th May 2026

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reveiwers	Details of significant changes
1.0	18th May 2026		

Contents

1 Introduction, Background and Purpose

The purpose of this SOP is to define the required procedures for conducting the CVC-TIP trial in a consistent, safe, and compliant manner. Specifically, it aims to:

- Ensure that all staff follow standardised methods for screening, consenting, and enrolling participants.
- Provide clear, step-by-step expectations for CVC insertion and ECG-guided tip positioning within the trial.
- Specify documentation and data-capture requirements to support accurate, high-quality dataset generation.
- Outline responsibilities for safety reporting, deviation management, and regulatory compliance.

The SOP should be used alongside the current approved version of the CVC-TIP trial protocol, local Trust research policies, and applicable regulatory frameworks. All personnel delegated to undertake trial activities are expected to follow this SOP to ensure consistent and compliant delivery of the study.

Accurate placement of a central venous catheter tip is essential to reduce the risk of complications such as arrhythmia, malposition, vascular injury, and thrombus formation. Traditional confirmation using post-procedure chest radiography introduces delays, incurs radiation exposure, and may not always provide immediate feedback to the operator.

ECG-guided tip positioning has emerged as a safe, real-time alternative method for confirming catheter location. The technique uses intracavitary ECG to detect changes in P-wave amplitude as the catheter approaches the cavo-atrial junction, allowing operators to adjust tip placement during insertion. Adoption of ECG guidance may reduce malposition rates, streamline workflow, and minimise reliance on radiography.

Standardising practice within the trial is essential to ensure data quality and to reliably assess the feasibility of the technique in order to inform a larger clinical trial.

2 Who Should Use This SOP

It is the responsibility of all staff who are involved with the CVC-TIP study to adhere to this SOP and to ensure it is communicated to other clinical staff undertaking this role. This includes the Chief Investigator other appropriately delegated staff. All training on this SOP should be documented in a study specific training log held by the Research Team.

3 When this SOP Should be Used

This SOP should be used when screening, consenting, randomising, performing trial-specific procedures, and completing the CRF for the CVC-TIP study. This includes reporting of adverse events.

4 Procedure(s)

4.1 Screening And Eligibility

All patients admitted to critical care at York Hospital — or expected to be admitted — who require a central venous catheter should be screened and added to the screening log. Paper-based eligibility forms will be available to complete for those who meet all the inclusion and none of the exclusion criteria.

4.2 Consent

Written informed consent must be obtained from the patient before enrolment into CVC-TIP. The enrolling clinician is responsible for confirming that the patient has the capacity to consent and has been provided with the current Participant Information Sheet (PIS). Adequate time should be given for the patient to read the information, ask questions, and make an informed decision. If a patient is to be intubated and ventilated as a part of their care, but has capacity prior to this, they can be approached and consented for the study.

Once informed consent has been obtained and the consent form signed, it should be photocopied accordingly: the original must be retained in the Investigator Site File, one copy provided to the participant, and one copy filed within the participant's medical notes. If a participant loses capacity following consent, they may remain in the study. Participants are free to withdraw from the study at any time without providing a reason. It is essential that the participant's medical notes clearly document confirmation of eligibility, as well as the upload and filing of the PIS, signed consent form, and any other associated study documentation.

4.3 Randomisation

After the patient has been confirmed as eligible, and there is appropriate signed consent, the investigator can proceed to randomisation. This is performed using REDCap and is available 24 hours a day, 7 days a week. If web-based randomisation is not available (e.g. hospital server issues, internet connectivity), randomisation cannot be performed. CVC insertion should not be delayed and this should be clearly documented in the screening log.

Following completion of Screening and Eligibility eCRF, the patient can be randomised into one of the three study arms, using the "Randomize" button on the "Randomisation" eCRF. The patient will be randomised into either: -

- Standard care (CVC insertion in either right or left internal jugular vein at the clinician's discretion)
- Right internal jugular vein CVC with intracavity ECG and thoracic point of care ultrasound
- Left internal jugular vein CVC with intracavity ECG and thoracic point of care ultrasound

Following randomisation, the investigator will record this in the patient's record on the ICU EPR using a dedicated form.

4.4 CVC Insertion

Once randomised, CVC insertion can proceed. This should be performed as per the local trust CVC insertion policy. Please note that all patients will have a post-procedure chest x-ray (CXR), regardless of which arm they are randomised into.

4.4.1 Standard Care

CVC insertion should be completed, the line sutured in place and a dressing placed over the insertion site as per the local protocol. A chest x-ray should then be requested before the CRF is completed. It is important to record the date and time of when the insertion was started and when it was finished (dressing applied) at the time of the procedure. All recorded data is to either be directly entered into the eCRF (REDCap), or on paper CRFs which will be transcribed into the eCRF by a member of the study team later.

4.4.2 Intracavity ECG

If the patient is randomised to either of the intracavity ECG arms, the patient will require intracavity ECG monitoring during the procedure. The equipment is kept on a dedicated trolley which will be locked away. After preparing equipment for CVC insertion, the operator will also need: -

- Pilot Tablet
- Pilot USB ECG Interface
- Pilot ECG Leads
- Vygocard 2 Sterile ECG Connector
- Bionector x1
- 10mls 0.9% Sodium Chloride

Before donning sterile precautions for CVC insertion, the Pilot tablet and ECG leads should be set up as per the study specific training "***CVC-TIP Training – Intracavity ECG***".

Intracavity ECG is to be performed **after** the guidewire has been removed but **before** the central venous catheter is sutured in position. The procedure is performed as per the study specific training "***CVC-TIP Training – Intracavity ECG***".

It is important to record the date and time of when the insertion was started, when intracavity ECG was started, when intracavity ECG was complete and when central venous catheter insertion was finished (dressing applied) at the time of the procedure. All recorded data is to either be directly entered into the eCRF (REDCap), or on paper CRFs which will be transcribed into the eCRF by a member of the study team later.

4.4.3 Thoracic Point of Care Ultrasound

If a participant has been randomised into the thoracic point of care ultrasound arm, this is to be performed **after** the CVC has been sutured in place and a dressing applied, but before a chest x-ray is performed.

The procedure will be performed as per the "***CVC-TIP Training – Thoracic Point of Care Ultrasound***".

It is important to record the date and time of when the thoracic point of care ultrasound was started and when thoracic point of care ultrasound was complete at the time of the procedure. All recorded data is to either be directly entered into the eCRF (REDCap), or on paper CRFs which will be transcribed into the eCRF by a member of the study team later.

4.5 Post-procedure Chest X-Ray

All patients, regardless of randomisation outcome, require a post-procedure chest x-ray. For those in the intervention arm, this will be performed after intracavity ECG and thoracic point of care ultrasound have been performed. It is important to record the date at time of when the CXR was requested, when it was performed and when it was reviewed for confirmation of the position of the central venous catheter tip. All recorded data is to either be directly entered into the eCRF (REDCap), or on paper CRFs which will be transcribed into the eCRF by a member of the study team later.

4.6 Case Report Form (CRF)

The CRF should be completed as close to procedure completion as possible. Paper copies of the CRF (pCRF) will be provided if the eCRF cannot be completed at the time of the procedure. These will need to be transcribed onto REDCap by a member of the study team. It is important to record the date and time of each step as described in the SOP and on the CVC Insertion CRF.

Adverse events and device deficiencies occurring during trial procedures must be documented in the CRF and reported in accordance with the CVC-TIP protocol and sponsor safety reporting procedures.

4.7 Protocol Deviations

Any deviation from this SOP or the approved protocol must be documented. Deviations should be reported to the chief investigator as soon as identified. Significant deviations affecting participant safety, consent, or data integrity should be escalated to the sponsor and managed as per the sponsor's protocols.

5 Related SOPs and Documents

Refer to SIV training slides and product literature.

6 Appendix A – Abbreviations

CRF	Case Report Form
CVC	Central Venous Catheter
CXR	Chest X-ray
ECG	Electrocardiogram
eCRF	Electronic Case Report Form
IC-ECG	Intracavity Electrocardiogram
ICF	Informed Consent Form
IJV	Internal Jugular Vein
ISF	Investigator Site File (This forms part of the TMF)
pCRF	Paper Case Report Form
PIS	Participant Information Sheet
POCUS	Point-of-care Ultrasound
SOP	Standard Operating Procedure

7 Appendix B – CVC-TIP SOP Flowchart