



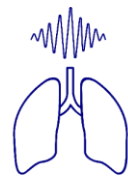
Scan for the UK NAVA
randomisation wizard



UK NAVA Participant Recruitment Checklist

Recruitment

No#	Task	Guidance	Done
1	Screen Patient	- Screen patients who meet the inclusion criteria against the exclusion criteria. - Update patient's medical notes to confirm eligibility	☐
2	Complete Screening Log	Enter any ineligible patients on the screening log	☐
3	Identify if there is a consultee available and assess urgency	- Identify a Personal or Professional Consultee if available - If a consultee is not available, or there is an urgent need to start the intervention, continue to step 5 in order to proceed with deferred consent	☐
4	Obtain Consultee Agreement	- If a personal or professional consultee is available, provide the relevant Consultee Information Sheet and the CoReCCT DIL. Use the CoReCCT Consultee Declaration Form for consultee agreement. - If verbal/remote agreement is obtained, a witness must be present	☐
5	Ensure equipment availability	Ensure a NAVA module and catheter is available for use if the participant is randomised to the NAVA technology arm	☐
	Check co-enrolment list	https://warwick.ac.uk/confederation/health/co-enrolment/	☐
6	Randomise	- Complete the randomisation wizard in the UK NAVA database (QR code at top of page) - Randomisation must be performed by someone who has been appropriately trained (either delegated on UK NAVA Delegation Log or listed on Clinical Randomisers log)	☐
7	Key tasks	- If participant is randomised to NAVA Technology arm, ensure NAVA Catheter is placed within 6 hours. Initiate safety checks, position check and NAVA Monitoring - If participant is randomised to Standard Care arm, ensure no NAVA catheter is present	☐
8	Key admin	- Document participant's TNO and trial arm allocation in medical notes - If deferred consent has been used, ensure a Consultee is approached within 72 hours if possible	☐



UK NAVA

Data Collection & Follow Up

No#	Task	Guidance	Done
1	Consent Wizard	If the participant has been randomised under deferred consent approach a professional or personal consultee at the earliest practical opportunity, then complete the Consent Wizard to confirm details	☐
2	Consent Considerations	If the participant has been randomised with professional consultee agreement approach personal consultee for their opinion at the earliest practical opportunity, then complete the Consent for Continued Participation Form	☐
3	Baseline Data	- Complete the following forms in the Core Database immediately after randomisation: * Core Contact Details Form * Core Baseline Form - Complete the following in the UK NAVA Database immediately after randomisation: * UK NAVA Baseline Form	☐
4	FOR NAVA TECHNOLOGY ARM ONLY: Record the Patient Neural Drive (EDI Max)	Record hourly EDI Max values using the UK NAVA Bedside Tool or on your own charts	☐
5	Complete Daily Data Forms	Complete the daily data forms found in the UK NAVA Database.	☐
6	Regaining of capacity	Once the participant has regained sufficient capacity, approach for ongoing consent then complete the Consent for Continued Participation Form	☐
7	When Intervention Ends	- Confirm if the participant has experienced any pre-specified complications on the Pre-specified Complications Form on the UK NAVA database - For intervention patients only, complete the End of Intervention Form on the UK NAVA database	☐
8	Hospital Discharge	Complete remaining CRFs in the Core Database	☐
9	At 2 and 6 Months	- When requested by Warwick CTU, complete relevant Participant Status Form in the Core Database - Aim to complete the form within 48 hours of request.	☐