Scan for the UK NAVA randomisation wizard

UK NAVA

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	☐

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.	☐