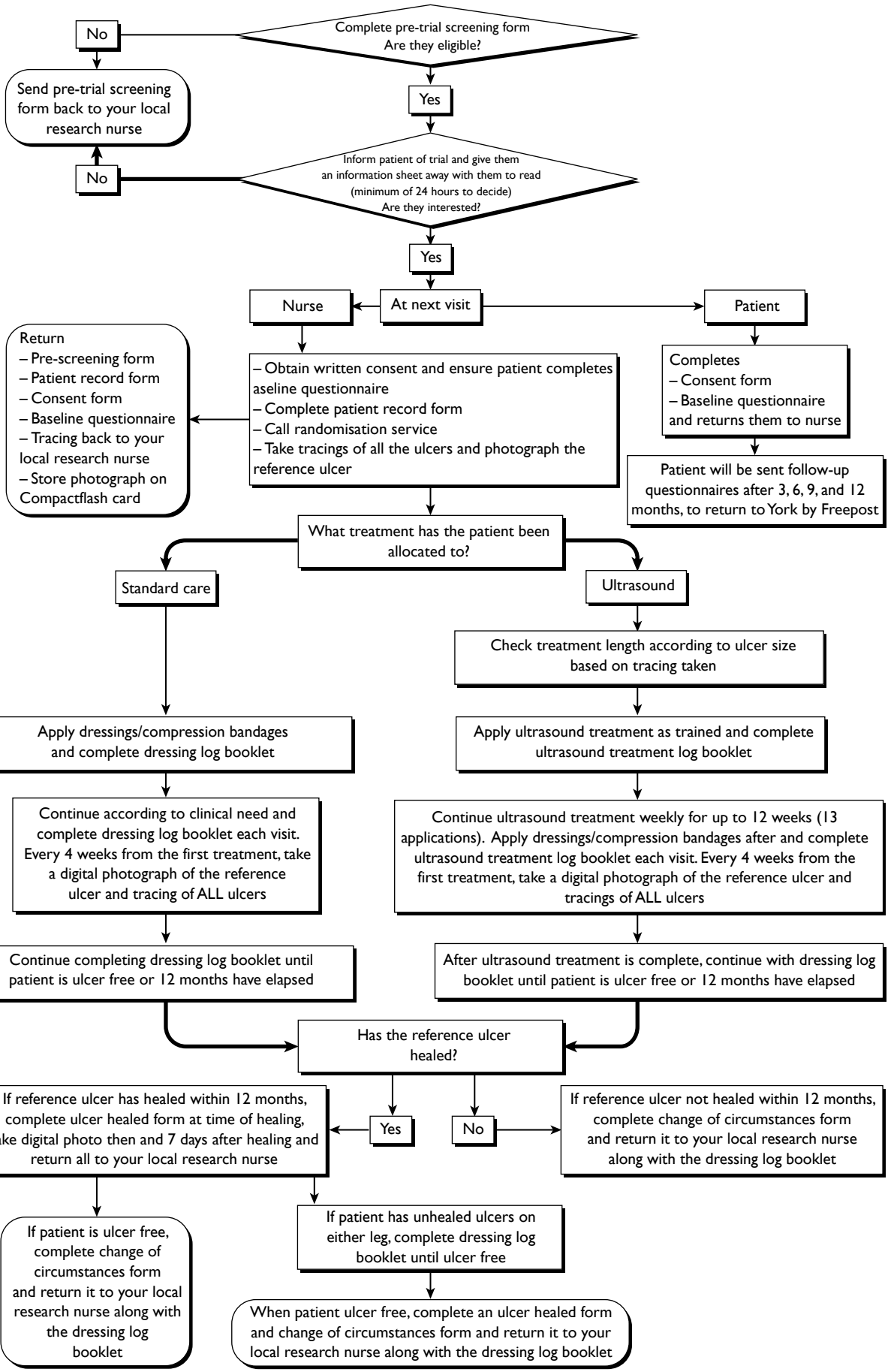
No
Complete pre-trial screening form
Are they eligible?
Send pre-trial screening form back to your local research nurse
Yes
No
Inform patient of trial and give them an information sheet away with them to read (minimum of 24 hours to decide)
Are they interested?
Yes
Nurse
At next visit
Patient
Return
– Pre-screening form
– Patient record form
– Consent form
– Baseline questionnaire
– Tracing back to your local research nurse
– Store photograph on Compactflash card
– Obtain written consent and ensure patient completes aseline questionnaire
– Complete patient record form
– Call randomisation service
– Take tracings of all the ulcers and photograph the reference ulcer
Completes
– Consent form
– Baseline questionnaire
and returns them to nurse
Patient will be sent follow-up questionnaires after 3, 6, 9, and 12 months, to return to York by Freepost
What treatment has the patient been allocated to?
Standard care
Ultrasound
Check treatment length according to ulcer size based on tracing taken
Apply dressings/compression bandages and complete dressing log booklet
Apply ultrasound treatment as trained and complete ultrasound treatment log booklet
Continue according to clinical need and complete dressing log booklet each visit. Every 4 weeks from the first treatment, take a digital photograph of the reference ulcer and tracing of ALL ulcers
Continue ultrasound treatment weekly for up to 12 weeks (13 applications). Apply dressings/compression bandages after and complete ultrasound treatment log booklet each visit. Every 4 weeks from the first treatment, take a digital photograph of the reference ulcer and tracings of ALL ulcers
Continue completing dressing log booklet until patient is ulcer free or 12 months have elapsed
After ultrasound treatment is complete, continue with dressing log booklet until patient is ulcer free or 12 months have elapsed
Has the reference ulcer healed?
If reference ulcer has healed within 12 months, complete ulcer healed form at time of healing, take digital photo then and 7 days after healing and return all to your local research nurse
Yes
No
If reference ulcer not healed within 12 months, complete change of circumstances form and return it to your local research nurse along with the dressing log booklet
If patient is ulcer free, complete change of circumstances form and return it to your local research nurse along with the dressing log booklet
If patient has unhealed ulcers on either leg, complete dressing log booklet until ulcer free
When patient ulcer free, complete an ulcer healed form and change of circumstances form and return it to your local research nurse along with the dressing log booklet

Below is a summary of what completed paperwork should be returned to which person, for each given scenario of patient involvement.

Patient not eligible or not interested at the first mention of trial	Return to your local research nurse: ➢ A completed and signed **Pre-screening Form**
Patient eligible in principle, but unsure, then not interested after 48 hours	Return to your local research nurse: ➢ A completed and signed **Pre-screening Form**
Patient eligible in principle, interested enough to attend full explanation but then not interested	Return to your local research nurse: ➢ A completed and signed **Pre-screening Form**
Patient fully eligible and consenting	Return to your local research nurse: ➢ A completed and signed **Pre-screening Form** ➢ A completed and signed **Patient Record Form** ➢ A signed and witnessed **Patient Consent Form** ➢ A completed **Patient Baseline Questionnaire** ➢ A completed **Tracing** of ulcer
Patient's reference ulcer has healed and there are no other ulcers **The patient is now completely ulcer free**	Return to your local research nurse: ➢ A completed **Ulcer Healed Form** ➢ Card with **digital photos** of reference ulcer site taken at time of healing and also 7 days after healing ➢ A completed **Change of Circumstances Form** ➢ A completed **Dressing or US Treatment Log Booklet**
Patient's reference ulcer has healed, but they still have other ulcers	Return to your local research nurse: ➢ A completed **Ulcer Healed Form** ➢ Card with **digital photos** of reference ulcer site taken at time of healing and also 7 days after healing
Change in patient's circumstances Including: treatment withdrawals, ulcer deterioration, adverse reactions, hospitalisation, patient death and lost to follow-up.	Return to your local research nurse: ➢ A completed **Change of Circumstances Form**
Patient has had an adverse event	Return to your local research nurse: ➢ A completed **Change of Circumstances Form** **ALSO** ➢ If non-serious - Inform your local research nurse. With the assistance of your local research nurse, complete a **Non-serious Adverse Event Form**. The local research nurse should return this form to the York Trials Unit within 5 days. ➢ If serious - Inform your local research nurse **immediately**. Your local research nurse should inform the York Trials Unit by telephone within 24 hours. With the assistance of the local research nurse, the Local Investigator should complete and sign a **Serious Adverse Events Form**. This form should be faxed to the York Trials Unit within 48 hours.

Other forms you have been provided with are:

Record of data collected for a recruited patient	To act as a reminder and for you to record which data should be recorded at each visit to a patient participating in VenUS III. This form should be kept at the front of the patient's records and does not need to be returned to anyone.