

SOS IVR Phone Line

IVR LIVE phone number: 024 7610 0792

IVR TRAINING phone number: 024 7693 2090

The SOS Interactive Voice Response system (IVR) is for randomising participants to the study, without the requirement of a database login or immediate computer access.

There are 2 phone lines. One for recruitment of participants to the LIVE database, and a separate one for TRAINING purposes only.

Requirements for using IVR

IMPORTANT – Training log sign-off required:

- You must have completed trial training
 - o SIV slides and/or full protocol training or
 - o Targeted training – patient recruitment and trial interventions document
[Training Resources \(warwick.ac.uk\)](https://www.warwick.ac.uk)
- You site PI should have signed the SOS_PIDeclarationForDelegationOfDuties_V1.0_12Jan23 document which confirms they are happy for clinically trained staff working on ICU, who have been appropriately trial trained, to randomise patients.

Steps to randomise a participant to the LIVE database using IVR:

1. Complete the paper randomisation form CRF03 first

- Once patient eligibility has been confirmed, complete the paper randomisation form CRF03.

2. Dial in to the LIVE IVR randomisation line

- Dial the LIVE IVR phone number (024 7610 0792)
- You will be asked to enter your site's 5-digit user ID (pin) which the trial team will have provided you with
 - o Each site's pin is linked to a person record i.e. First name: SITE & surname: IVRUSER
- You can press * to go back to the previous question or 0 to go back to beginning

3. Answer the IVR questions

- You will be asked if the patient is eligible
 - o Dial 1 for NO
 - o Dial 2 for YES
- You will be asked to dial the patient's age
 - o Dial the patient's age (up to 3 digits accepted)
- You will be asked to enter the best GCS motor score prior to intubation or sedation
 - o Dial the number associated with the GCS motor score (present on the paper CRF03 and will also be read out by the automated system)
- You will be asked to enter the pupillary response prior to intubation
 - o Dial the number associated with the pupillary response (present on the paper CRF03 and will also be read out by the automated system)
- You can press * to go back to the previous question or 0 to go back to beginning

4. Confirm the randomisation

- You will be asked to confirm that the details you selected are correct
 - o Dial 1 to confirm all the information is correct
- You will be provided with the participant's 4-digit trial number and the treatment allocation

4. Complete database forms

- Once you have the TNO and treatment allocation, these details will automatically be generated for the participant TNO on the LIVE database
- As soon as possible please complete the following on the LIVE database for that TNO:
 - o Randomisation form: complete 'Randomisation completed by' and 'Date completed'
 - o Screening & Eligibility form: complete whole form and send signed paper copy to sostrial@warwick.ac.uk

Steps to randomise a test participant to the TRAINING database using IVR:

Follow the same steps as above, HOWEVER, please remember to use the TRAINING IVR phone number instead (024 7693 2090) and training pin code.