



PhEAST Working Practice Document **Title: Manual Randomisation, No. 003**

- In the event of technical problems, which cause computerised randomisation failure, sites should seek to randomise a patient over the telephone.
 - The technological failure may be either at the site's end with failure of hospital systems, or with University systems in the UK.
 - The PhEAST Trial Office can be contacted in UK working hours (excluding weekends and public holidays) on: +44 115 823 1255. Emergency telephone numbers for randomisation are available on the PhEAST trial documents website.
 - A written note of these emergency contact numbers should be kept as the website may also be unavailable due to technical failure. These numbers may alter from time to time with staff changes and efforts should be made to keep an up to date list.
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- **In order to randomise a patient over the telephone, sites will be required to provide all information requested on the Randomisation CRF.** When providing details over the telephone you will be required to confirm that the patient fulfils all the inclusion and none of the exclusion criteria.
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- A paper copy of the randomisation CRF will need to be completed and scanned to the PhEAST inbox pheast@nottingham.ac.uk.
 - If the technological failure is at the trial site, the trials office will enter the data into the system on behalf of the site. Advice regarding treatment allocation will be given over the phone.
 - If the technological failure is at the university site, manual randomisation will be performed. Advice regarding treatment allocation will be given over the phone.
 - Sites should not randomise a further patient until the database has been updated.
 - Please take particular care to ensure that the patient fulfils all the inclusion and none of the exclusion criteria. The built-in checks with the computerised system are not available with telephone randomisation.