

Preparing the trial documents for printing

The trial documents can be downloaded from the PhEAST website documents page. Please download the documents from here to ensure you are using the current version of the document. <https://stroke.nottingham.ac.uk/pheast/docs/>

Document Title	Preparation Requirements
PhEAST Long PIS	<ul style="list-style-type: none"> Delete [local letterhead to be added] and insert the site's logo/header Enter name of local researcher (PI) Delete [please provide the contact details of PALS for the hospital] and insert these details Insert name and contact details of local research team and local PI
PhEAST Aphasia Friendly PIS & ICF	<ul style="list-style-type: none"> Delete [local header] and insert the site's logo/ header
PhEAST Participant Consent Form	<ul style="list-style-type: none"> Delete [form to be printed on local headed paper] and insert the site's logo/header Do not enter Name of Researcher as the team may change over time, this must be handwritten in at the time of consent along with the name of the participant Enter version number and date of PIS used
PhEAST Participant Re-Consent Form	<ul style="list-style-type: none"> Delete [form to be printed on local headed paper] and insert the site's logo/header Do not enter Name of Researcher as the team may change over time, this must be handwritten in at the time of consent along with the name of the participant Enter version number and date of PIS used
PhEAST Participant Re-Consent PIS (Scot only)	<ul style="list-style-type: none"> Delete [local letterhead to be added] and insert the site's logo/header Enter name of local researcher (PI) Delete [please provide the contact details of PALS for the hospital] and insert these details Insert name and contact details of local research team and local PI

Document Title	Preparation Requirements
PhEAST Consultee / Legal Rep Information Sheet	<ul style="list-style-type: none"> Delete [local letterhead to be added] and insert the site's logo/header Enter name of local researcher (PI) Delete [please provide the contact details of PALS for the hospital] and insert these details Insert name and contact details of local research team and local PI
PhEAST Consultee / Legal Rep Declaration / Consent Form	<ul style="list-style-type: none"> Delete [form to be printed on local headed paper] and insert the site's logo/header Do not enter Name of Researcher as the team may change over time, this must be handwritten in at the time of consent along with the name of the participant Enter version number and date of PIS used
PhEAST Consultee / Legal Rep Tel Declaration / Consent Form	<ul style="list-style-type: none"> Delete [form to be printed on local headed paper] and insert the site's logo/header Do not enter Name of Researcher as the team may change over time, this must be handwritten in at the time of consent along with the name of the participant Enter version number and date of PIS used

Document Title	Preparation Requirements
PhEAST Informant Information Sheet	<ul style="list-style-type: none"> • Delete [local letterhead to be added] and insert the site's logo/header • Enter name of local researcher (PI) • Delete [please provide the contact details of PALS for the hospital] and insert these details • Insert name and contact details of local research team and local PI
PhEAST Informant Consent Form	<ul style="list-style-type: none"> • Delete [form to be printed on local headed paper] and insert the site's logo/header • Do not enter Name of Researcher as the team may change over time, this must be handwritten in at the time of consent along with the name of the participant • Enter version number and date of PIS used
PhEAST Informant Tel Consent Form	<ul style="list-style-type: none"> • Delete [form to be printed on local headed paper] and insert the site's logo/header • Do not enter Name of Researcher as the team may change over time, this must be handwritten in at the time of consent along with the name of the participant • Enter version number and date of PIS used •

Note: remember when the participant completes the written follow on consent the boxes need to be initialled by the participant (if they have capacity to do do). Please do not tick the boxes.

GP Letter

After a participant has been enrolled into the PhEAST trial you will need to send a letter to their GP informing them of their patient's participation in the trial.

Preparing the template: Delete [form to be printed on local headed paper] and insert the site's logo/header. Insert the local research teams contact details.

Do not print GP templates, the letters will be specific for each participant. When completing the GP letter please enter

- Date letter is typed
- GP address
- Name of GP
- Name of patient
- DOB of patient
- Name of local PI, job title and signature

Don't forget to include a copy of the participant information sheet to be sent with the letter.

Please save the letter to the participant's medical records as well as their CRF.

Documents ready for enrolment

Once you have localized the above documents:

We recommend you print a small batch of each document ready for the consent process and make sure all the local team know where these documents are stored. Please make sure you are using the most up to date version before consenting the participant.

Contact

If you require any further assistance in preparing the trial documentation please contact the trial team pheast@nottingham.ac.uk

