PhEAST Working Practice Document
Title: Consent, No. 002

This document is intended to give guidance on informed consent in the PhEAST trial, including which documents are to be used at each stage of the process.

This document provides guidance on the following situations;

- Patient has capacity to provide consent
- Patient has capacity but is unable to sign informed consent form
- Patient lacks capacity to give consent
  - Relative present on ward
  - Relative not present on ward
  - Relative not available to be appointed
- Patients who regain capacity to consent.

Summary for consent with respect to PhEAST:

1. Consent for the PhEAST study can be taken by the investigator (or designee including doctors, nurses, speech therapists and research health professionals) provided that they have received appropriate training in the trial regimen – particularly the inclusion and exclusion criteria and they can answer all questions that may arise from the potential participant or relative.

2. All staff that are able to take consent for the trial, must have consent specified on the Site Delegation/Signature Log which needs to be signed/approved by the Principal Investigator.

3. The Principal Investigator (PI), or another appropriately trained researcher who is trained on PhEAST and is on the site's PhEAST delegation/signature log, should be available if the patient, relative who is providing the declaration form, or site staff require further information.

4. The PI, or another appropriately trained health professional as defined above should make a comment in the notes that the patient fulfilled the inclusion criteria and that the patient, or relative gave consent. If using independent physician consent (England, Wales and Northern Ireland only), sites must document that attempts were made to contact a personal consultee. Copies of the information sheet and consent form used should be filed in the patient medical notes, and another copy given to the participant / consultee if applicable.

5. The use of independent physician consent can only be used in England, Wales and Northern Ireland in a situation where all

attempts at contacting a personal consultee have failed. The independent physician must not be on the trial delegation log and must not be affiliated in any way with the PhEAST trial. If contact is then made with a relative, or the patient regains capacity, re-consent must take place for continued participation in the trial. Scottish sites must not use independent physician consent.

Once it has been decided that the potential participant meets the eligibility criteria, the following consent procedure should be followed, in each situation, using the documents highlighted.

England / Wales / Northern Ireland

Situation	***Documents to be used***
Patient has capacity to provide consent	Participant Information Sheet and Consent Form.
Patient has capacity but is unable to sign the informed consent form	Participant Information Sheet and Consent Form, witnessed and signed by an independent third party.
Patient has capacity but is suffering with aphasia	Aphasia Friendly Participant Information Sheet and Consent Form.
Patient lacks capacity: *1.Relative present on ward*	Consultee Participant Information Sheet and Consultee Declaration Form.
2. Relative not present on the ward but available by telephone	Consultee Participant Information Sheet (emailed or posted) and Consultee Telephone Declaration Form, witnessed and signed by an independent third party.
3. Relative not available to be appointed	Consultee Participant Information Sheet and Consultee Declaration Form (using independent physician consent).
Patients who regain capacity to consent	Participant Information Sheet and Participant Re-consent form.

Scotland

Situation	***Documents to be used***
Patient has capacity to provide consent	Participant Information Sheet and Consent Form.
Patient has capacity but is unable to sign the informed consent form	Participant Information Sheet and Consent Form, witnessed and signed by an independent third party.
Patient has capacity but is suffering with aphasia	Aphasia Friendly Participant Information Sheet and Consent Form.
Patient lacks capacity *1.Relative present on ward* *2. Relative not present on the ward but available by telephone*	Legal Representative Participant Information Sheet and Legal Representative Consent Form. Legal Representative Participant Information Sheet (emailed or posted) and Legal Representative Telephone Consent Form, witnessed and signed by an independent third party.
Patients who regain capacity to consent	Participant Recovered Capacity (re-consent) Information Sheet and Participant Re-consent form.