Appendix L. Austrian Consent Process

For study centers in Austria the following possibilities to obtain informed consent are valid all of which follow Austrian health authorities' regulations and general rules of good clinical practice.

a) Informed consent to participate is given by the fully aware patient after reading, comprehending, and signing the patient's study information and the declaration of consent.
b) For patients who do not have the capacity to comprehend the informed consent process (for example patients with severe receptive aphasia) and who have a legal representative responsible for health issues, consent can be given by this legal representative.
c) Patients who lack the capacity to comprehend the informed consent process (i.e. severe receptive aphasia) and who do not have a legal representative can be included if the investigator sees a clear individual advantage for the patient by participation in the trial. [1]

[1] The PhEAST study entails the advantage of planned, specialized and documented assessments of the patient's functional state regardless of trial group allocation. By these means additional needs during the hospital stay can be identified especially in patients who are unable to communicate verbally their therapeutic needs. In addition, the follow-up survey after three and twelve months goes beyond the usual hospital follow up schedule and can also provide therapy-relevant information.

In this procedure the patient’s consent must be signed by the clinical investigator and a second physician who is not a member of the study team.

Formal information and signed consent must be sought at later date as soon as possible after improvement of communication abilities.

d) d) Patient who are able to consent - but not capable of signing (for example if dexterity is impaired by paresis) can express their consent in spoken words in front of a witness who is not part of the study team. The consent form must be signed then by the clinical investigator and this independent witness. Signature of declaration of consent form must be sought at later date as soon as possible.