PhEAST Working Practice Document
Title: Blinding, No. 08

It is important that the outcomes of PhEAST are reliable and we avoid any conscious or sub-conscious bias.

Investigators, participants and their families will be unblinded to treatment. Although there is no sham (placebo) treatment, many participants may be unaware of their treatment assignment as they have suffered a severe stroke and will have a standard nasogastric tube inserted.

Those involved in outcome assessment must be blinded to treatment assignment i.e. they must not know whether a participant was in the treatment or control group.

All participants should receive a bedside swallowing assessment by a speech and language therapist (SLT) at day 14 (may be completed day 13-16). This SLT must be blinded to treatment assignment. To ensure that the SLT is blinded, it would be preferable that they do not work in the stroke unit (to reduce the chance of accidental unblinding), but they should be competent in dysphagia management and have some experience of neurogenic dysphagia.

The blinded SLT should not go through the medical notes of the participant but can instead ask an unblinded member, ideally from the ward unblinded SLT team, or the research team, or a member of the medical team if a SLT is not available to give them an update on the participant (any relevant medical history, progress with oral intake, etc.) so that they can complete their assessment. They can also liaise with the nursing team regarding the patient's progress with oral intake, etc. The blinded SLT should remind each person they are talking to not to reveal the treatment assignment of the participant when relaying information to the blinded SLT.

Once the SLT has done their day 14 (may be completed day 13-16) bedside assessment, they can either go on to complete all day 14 (13-16) outcomes, or this can be picked up by a blinded researcher. If the latter, the blinded researcher will use the information from the blinded SLT bedside assessment to complete the day 14 DSRS (13-16) (FOIS and FSS will be calculated automatically from the DSRS). If the researcher is only entering the data provided to them by the blinded SLT who undertook the bedside assessment, and they are therefore unblinded, a comment should be added on the eCRF to document this.

In order to assist with the process of blinding, the Phagenyx catheter must be removed before day 14 (13-16) assessment (and replaced with standard NGT if required).