###  *(Form to be printed on local headed paper)*

**Participant Information Sheet – Legal Representative (Welfare Attorney (WA)/Welfare Guardian (WG)/Nearest Relative (NR))**

(Final version 6.0: 07/03/2023)

**IRAS Project ID: 306761**

Title of Study: **Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)**

Name of Chief Investigator: **Prof. Philip Bath**

Name of Researcher(s): xxxxxxxxxx

**Invitation**

Your ward/relative is being invited to take part in a research study. We are therefore asking you, as someone who knows them well, to advise us on whether they would wish to take part were they able to make this decision. We ask you to set aside your own views and consider only what their wishes and feelings would have been. Any advance decisions they may have made which you are aware of should take precedence.

Before you decide whether you agree to their participation it is important for you to understand why the research is being done and what it will involve. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

**Who can act as a legal representative?**

Where people cannot take the decision to consent to be involved in a research project then a legal representative must be appointed. ***In the first instance the legal representative should be the participant’s welfare attorney (WA) or welfare guardian (WG), if not appointed this should be the participant’s nearest relative (NR).***

The capacity to make a decision will be assessed in the initial conversation by clinical staff/research team identifying the patient as a trial participant. This will normally involve a 3 simple question approach following a brief outline of the trial, to establish whether the patient understands why the trial is being done, what the treatment will be and what will happen after the trial ends.

**What is the role of the legal representative (WA/WG/NR)?**

The legal representative (WA/WG/NR) is asked to give consent on behalf of an adult lacking capacity to do so for themselves, considering what the participant themselves would want. Legal Representatives (WA/WG/NR) will be provided with information about the research project and will be given the opportunity to discuss it and their role as legal representative (WA/WG/NR). All legal representatives (WA/WG/NR) must be able to understand their role and be willing to undertake it.

**What is the purpose of the study?**

The purpose of this study is to find out whether a regular course of treatment of Pharyngeal Electrical Stimulation (PES), stimulation of nerves in the throat that may have been damaged by a stroke, can help recovery back to eating and drinking by mouth. In four previous studies of PES involving stroke patients, the treatment devices were found to be safe and good performance was achieved in over 200 patients with no device-related adverse events being observed. The PES treatment can therefore be described as “low risk”. The study will also look at cognition and whether this is affected when you have had a stroke.

**Why has my ward/relative/person you are consenting for been invited?**

Your ward/relative is being invited to take part because they have been diagnosed as suffering from ‘neurogenic dysphagia’. This is the medical term for swallowing difficulties that are caused by injury or diseases that affect the brain and nerves controlling swallowing. Swallowing problems can lead to chest infections and the need to stay in hospital longer and can significantly affect quality of life. As your ward/relative may need to have or already has a nasogastric (in the nose) feeding tube due to their swallowing difficulties, they may be suitable to take part in this study. We are inviting 800 participants like your ward/relative to take part.

**Does my ward/relative/person you are consenting for have to take part?**

We would like you to think very carefully about whether or not this person would have wanted to join the study. If your opinion is that they would have decided to take part, you would be given this information sheet to keep and be asked to sign a consent form indicating your view allowing your ward/relative/person you are consenting for, to participate in the study. If you later decide that they no longer wish to take part, please inform us and they will be withdrawn from the study. You do not need to give a reason and it will not affect the standard of care your ward/relative/person you are consenting for, receives.

**What will happen to my relative if they take part?**

The doctor/care team will carefully check if your ward/relative is able to take part. For this they will check their medical records and may ask a series of questions related to the condition of your ward/relative. Some conditions may make it unsafe for them to receive PES such as having a pacemaker, being pregnant or requiring continuous oxygen therapy. The team will check all of this and let you know if it would be suitable for your ward/relative to take part.

This is a randomised control trial, meaning that after agreeing to participate, some patients will be allocated to receive the PES-treatment in addition to standard management for swallowing difficulties (dysphagia) while others will still receive the standard care management but without PES.

The patient or their doctor can’t decide which they will receive and it will be determined at random by a computer. For those participants allocated to standard care without PES, the same data will be collected and the same follow up procedures will be carried out.

If your relative is randomised to receive the PES-treatment, they may need additional chest X-rays to confirm that the catheter / NG tube is in the right place.

‘Pharyngeal Electrical Stimulation’ (PES) treatment is delivered using a commercially available medical device attached to a nasogastric feeding tube (Phagenyx®, Phagenesis Ltd, Manchester UK). The device is referred to as an integrated catheter. The outer part is a sleeve that incorporates the electrodes to deliver the current; the inner core houses the actual nasogastric feeding tube.



The treatment will involve electrical stimulation of the integrated catheter at a level of stimulation that will be customised to each participant’s tolerance above a required threshold current. The treatment will be administered in one 10-minute session per day over a period of six days, only by PES-trained research staff (co-ordinators, nurses, speech and language therapists). To eliminate bias, they will not be involved in analysing the results. Treatment will be stopped if there is no further need for tube feeding.

Following the six days of PES treatment, a study researcher not involved in the treatment, will carry out a number of standard clinical stroke-related assessments. They will ask your ward/relative a few questions and examine their swallow, speech, eyesight, cognition, head, arms and legs to determine how the stroke has affected them. With your permission, they will record details of your ward/relative, condition, their test results and medications on a clinical log.

If you agree, we will send a letter to your ward/relative’s GP, informing them of their participation in the trial. We will also ask your permission to contact their GP or consult the NHS Information Centre to check on their health condition at three months, six months and 12 months after their stroke and to confirm their contact details.

A member of the research team will then contact them at Day 143 months, 6 months and 12 months after the treatment to carry out a repeat of the clinical assessments by questionnaire (via phone/email/post). This will take about 45 minutes to 1 hour.

**Cognition Sub-study**

The PhEAST trial will collect information on memory, thinking skills and mood. We would like to gather some of this information from the relatives of PhEAST participants, and so we would also like to invite you to take part in this aspect of the trial.

**Do I have to agree to take part?**

No, it is up to you to decide whether or not to agree to take part.  If you do agree, you will be given this information sheet to keep and be asked to sign a consent form. You will be free to withdraw at any time and without giving a reason.  If you withdraw we will no longer ask you to provide information on your relative but we will keep the information that we have already obtained. Deciding not to take part, or withdrawing from the study, will not affect the healthcare, or legal rights of your relative. If you decide not to take part or withdraw from the study, this will also not affect your relative’s participation in the PhEAST trial.

**What will the Study involve for me?**

**First assessment**: Will take place soon after your relative’s stroke. We will ask you to complete a short questionnaire about their memory, thinking skills or mood before the stroke.

**Second assessment**: Will take place 14 days after the baseline assessment, we will ask your relative about their health after the stroke, more questions about their memory, thinking and mood, and about their swallowing.  This will be done at the hospital if they are still an inpatient. We will also ask you some more questions about their memory, thinking and mood. This can be done by phone if you are not able, or do not want, to come to the hospital.

**3 months, 6 months and 12 months after stroke**: We will contact your relative’s GP to check that it is OK to contact them. We will then get in touch with you to ask about their recovery and their impression of their memory, thinking skills and mood and how the participant is coping. We can do this over the telephone.

If you would like to participate in this part of the trial we will ask you to sign a separate consent form for this. We will follow ethical and legal practice and all information about you and your relative will be handled in confidence.

**Expenses and payments**

Participants will not be paid to take part in the study.

**What are the possible disadvantages or risks of taking part?**

In general, all procedures in this study are well tolerated by people. Although the PES-treatment is “low risk”, it is not impossible that an unanticipated risk may occur during the clinical study, but the

chances of this happening are small and we have taken steps to make sure it is as safe as possible for your ward/relative to take part. We will watch everyone in the study for any side effects and keep a special close watch on any health event. Specifically, the risks and unwanted events that can come about, are listed as follows;

1. *Insertion of nasogastric tubes into the throat is part of standard dysphagia care:* The insertion of the treatment tubes through the nose can cause mild but temporary irritation of the nose or throat. Experienced staff will carry out this procedure to minimise the discomfort. There has been no incidence of harmful complications caused by the insertion of such tubes in previous studies.
2. *Electrical stimulation of the throat:* The electrical stimulation can sometimes cause a moderate warm sensation at the back of the throat but this sensation is not painful.
3. *Chest X-Ray:* As part of the study your relative may receive up to 3 chest X-rays, some of which they would not have had if they did not take part. X-rays are a form of ionising radiation and are used to create images of the body. The risk of exposure to radiation is that you may develop cancer some years in the future. 1 in 2 people in the UK will develop cancer at some point in their lifetime. Taking part in the study will increase the chance of this happening to your relative by only a very small amount.

**What are the advantages of taking part?**

We cannot promise the study will help your ward/relative, but the information we get from this study may help explain how to help with swallowing problems in the future. Their swallowing function may improve after the study treatment (this is only for patients who are randomised to receive the treatment). If we observe that their swallowing has improved during the study, we will discuss this with the medical care team.

**What happens when the research study stops?**

We would like to follow the progress of your ward/relative, at 3 months and 1 year. When all participants have been followed up, the trial results will be analysed and published in a medical journal. We will offer to send your ward/relative a copy of the results.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting NHS Complaints. Details can be obtained from your hospital. [please provide the contact details of PALS for the hospital/]

In the event that something does go wrong and your ward/relative is harmed during the research and this is due to someone's negligence then your ward/relative, may have grounds for a legal action for compensation against the University of Nottingham but your ward/relative, may have to pay their legal costs. The normal National Health Service complaints mechanisms will still be available to them.

**Will their taking part in this study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about your ward/relative will be handled in confidence.

If your ward/relative joins the study, we will use information collected about them and their medical records during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password-protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after the information and using it properly. Rights to access, change or move that information, are limited as we need to manage the information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard the rights of your ward/relative, we will use the minimum personally – identifiable information possible.

You can find out more about how we use the information of your ward/relative and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to your ward/relative/person you are consenting for, as a research participant and we will do our best to meet this duty.

All information which is collected about your ward/relative, during the course of the research will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database. Any information about your ward/relative, which leaves the hospital will have the name, address and CHI number of your ward/relative removed (anonymised) and a unique code will be used so that they cannot be recognised from it.

Where possible information about your ward/relative/person, which leaves the hospital will have their name, address and CHI number removed and a unique code will be used so that they cannot be recognised from it, however sometimes we need to ensure that we can recognise them to link the research data with their medical records so in these instances we will need to know their name and date of birth. We will also need this information if we need to follow up their medical records as part of the research, where we may need to ask the Government services that hold medical information about them (such as NHS Digital, the Office for National Statistics, among others) to provide this information to us. By signing the consent form you agree to the above.

The personal data (name, address, CHI number and contact details) of your ward/relative will be kept for 12 months after the end of the study so that we are able to contact them about the findings of the study (unless you advise us that your ward/relative does not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time the data of your ward/relative/person you are consenting will be disposed of securely. During this time all precautions will be taken by all those involved to maintain the confidentiality of your ward/relative, only members of the research team will have access to their personal data.

In accordance with the University of Nottingham’s, the Government’s and our funders’ policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that your ward/relative could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect the confidentiality of your ward/relative.

**What will happen if I do not want my ward/relative to carry on with the study?**

The participation of your ward/relative is voluntary and you are free to withdraw them at any time, without giving any reason, and without their legal rights being affected. They will continue to receive the best guideline-based treatment. If you withdraw your ward/relative we will no longer collect any information about them or from them but we will keep the information about your ward/relative/person you are consenting for that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard the rights of your ward/relative you are, we will use the minimum personally-identifiable information possible.

**Involvement of the General Practitioner/Family doctor (GP)**

If you agree, we will send a letter to your ward/relative’s GP informing them of their participation in the trial. We also ask your permission to contact their GP or check with the NHS Information Centre to check on the condition of your ward/relative, at 3 months and 1 year after their stroke and to confirm their contact details.

**What will happen to the results of the study?**

When all participants have been followed up, it is intended that the results of the study will be presented at conferences and published in medical journals so that we can explain to the medical community what our research results have shown. We will present the findings at national and international conferences: the UK Stroke Forum; European Stroke Organisation Conference; International Stroke Conference; World Stroke Conference.

The results will contribute to the National Institute for Health and Care Excellence (NICE) assessment of this technology. They may be used to apply to the necessary authorities to make the intervention widely available, if shown to be beneficial.

At the end of the trial, the Patient-Public Involvement representative will be supported in disseminating the results and participant and relative-facing materials will be published on the trial website.

Participants will not be identified in any report/publication.

**Who is organising and funding the research?**

This research is being organised by the University of Nottingham and is being funded by National Institute for Health Research (NIHR), the research arm of the NHS. The devices are being supplied by Phagenesis Limited (Manchester, U.K, the manufacturer of the PES-treatment. None of the research team members receive any payment beyond their normal salary for conducting the study.

**Who has reviewed this study?**

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect participant’s interests. This study has been reviewed and given favourable opinion by Scotland A Research Ethics Committee.

**Further information and contact details**

We are happy to answer any questions you may have relating to this study. Please ask the doctors or nurses on the ward, or the local principal investigator for further information.

Thank you very much for taking the time to read this leaflet.

**The member of the research team who gave you this information:**

Name:

Tel: (\_\_\_\_\_) \_\_\_\_\_\_[insert details]

**Local principal Investigator:**

Name:

Address:

Tel: (\_\_\_\_\_) \_\_\_\_\_\_ [insert details]

**If you would like to discuss this study with someone independent of the study, please contact:**

Name:

Telephone: xxxxx [insert details]

This will be a professional who has knowledge of the study but is completely independent of it.

**Chief Investigator:**

**Name: Prof Philip Bath**

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