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

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

(Final version 1.0 24/06/2022)

**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

**You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.**

**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 to take part?**

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.

**Why have I been invited?**

You have been invited to take part as your relative is taking part in the PhEAST trial. 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.

**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. Deciding not to take part, or withdrawing from the study, will not affect the healthcare, or legal rights of your ward/relative/person. 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 ward/relative/person’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 the participant 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 ward/relative/person’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.

**Expenses and payments**

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

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

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

If you join the study, we will use information you provide about your relative 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 you and your relative’s 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 your you and relative’s rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use you and your relative’s information 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 you and your relative as research participant’s and we will do our best to meet this duty.

All information which is collected about your 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 relative which leaves the hospital will have your relative’s name and address removed (anonymised) and a unique code will be used so that they cannot be recognised from it.

Where possible information about your relative which leaves the hospital will have their name and address 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.

Your relative’s personal data (address, telephone number) will be kept for 12 months after the end of the study so that we are able to contact you about the findings of the study and information about follow up studies (unless you advise us that your relative does not wish to be contacted). We will also keep your personal data (address, telephone number, email address) on record for 12 months after the end of the study, this is so we can contact you at the follow up time points, and we can contact you about the findings of the study.   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 your relative’s data will be disposed of securely.  During this time all precautions will be taken by all those involved to maintain your relative’s confidentiality, 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 you 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 your confidentiality.

Although what you say to us is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons.

**What will happen if I don’t want to carry on with the study?**

Your participation is voluntary and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. 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 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 your and your relative’s rights, we will use the minimum personally-identifiable information possible.

**What are the possible benefits of taking part?**

We cannot promise that taking part in this study will directly benefit you or your relative but the information we get from this study may help explain how to help with swallowing problems in the future.

**Are there possible disadvantages and risks from taking part?**

Some people may find the extra questions tiring and they will take up time.

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

We would like to follow the progress of your ward/relative, at 3 months, 6 months and 12 months. When all participants have been followed up, the trial results will be analysed and published in a medical journal. We will offer to send you and 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.

**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**

**Professor of Stroke Medicine**

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