NHS
Health Research Authority

**East of England - Essex Research Ethics Committee**
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

**Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval**

06 December 2021

Prof Philip Bath
Professor of Stroke Medicine
University of Nottingham
Stroke Trials Unit, Mental Health & Clinical Neurosciences
University of Nottingham,
D Floor, South Block, Queen's Medical Centre, Derby Rd. Nottingham
NG7 2UH

Dear Prof Bath

| | |
|---|---|
| **Study title:** | **Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)** |
| **REC reference:** | **21/EE/0252** |
| **Protocol number:** | **21068** |
| **IRAS project ID:** | **304658** |

The Research Ethics Committee (REC) reviewed the above application at the meeting held on 04 November 2021. Thank you for attending to discuss the application.

## Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

## Mental Capacity Act 2005 (England and Wales)

### *Relevance of the research to the impairing condition*

The Committee agreed the research was connected with an impairing condition affecting persons lacking capacity or with the treatment of the condition.

***Justification for including adults lacking capacity to meet the research objectives***

The Committee agreed the research could not be carried out as effectively if it was confined to participants able to give consent.

***Arrangements for appointing consultees***

After discussion the Committee agreed that reasonable arrangements were in place for appointing consultees with only a few minor adjustments to the consultee information sheet and consent forms needed.

***Balance between benefit and risk, burden and intrusion***

The Committee agreed that the research has the potential to benefit participants lacking capacity without imposing a disproportionate burden on them. All potential participants with or without mental capacity issues would have a naso-gastric tube in situ as part of standard care.

***Additional safeguards***

The Committee was satisfied that reasonable arrangements would be in place to comply with the additional safeguards set out in Section 33 of the Mental Capacity Act 2005 (England and Wales) and the equivalent Section 137 of the Mental Capacity Act (Northern Ireland) 2016).

***Information for consultees***

The Committee was satisfied that the information to be provided to consultees about the proposed research was adequate to enable consultees to give informed advice about the participation of persons lacking capacity.

**Good practice principles and responsibilities**

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it

has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

If you have not already included registration details in your IRAS application form, you should notify the REC of the registration details as soon as possible.

Further guidance on registration is available at: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

**N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months**.

During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19

studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

Clinical trial authorisation must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

The sponsor is asked to provide the Committee with a copy of the notice from the MHRA, either confirming clinical trial authorisation or giving grounds for non-acceptance, as soon as this is available.

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

**After ethical review: Reporting requirements**

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

**Ethical review of research sites**

NHS/HSC Sites

The favourable opinion applies to all NHS sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland)being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

**Approved documents**

The documents reviewed and approved at the meeting were:

| *Document* | *Version* | *Date* |
|---|---|---|
| Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [sponsor insurance] | | 26 July 2021 |

| | | |
|---|---|---|
| GP/consultant information sheets or letters [letter to GP, tracked changes] | 2.0 | 02 December 2021 |
| GP/consultant information sheets or letters [letter to GP, clean] | 2.0 | 02 December 2021 |
| IRAS Application Form [IRAS_Form_04102021] | | 04 October 2021 |
| IRAS Checklist XML [Checklist_04102021] | | 04 October 2021 |
| IRAS Checklist XML [Checklist_03122021] | | 03 December 2021 |
| Letter from funder [NIHR funding] | | 29 July 2021 |
| Letter from sponsor [sponsor letter] | | 04 October 2021 |
| Other [Protocol Appendix A_DSRS] | 1.0 | 30 September 2021 |
| Other [Protocol Appendix C_EAT-10] | 1.0 | 30 September 2021 |
| Other [Protocol Appendix D_FSS] | 1.0 | 30 September 2021 |
| Other [Protocol Appendix E_NIHSS] | 1.0 | 30 September 2021 |
| Other [Protocol Appendix F_GCS] | 1.0 | 30 September 2021 |
| Other [Protocol Appendix G_EuroQoL] | 1.0 | 30 September 2021 |
| Other [Protocol Appendix H_mRs] | 1.0 | 30 September 2021 |
| Other [Protocol Appendix I_Barthel] | 1.0 | 30 September 2021 |
| Other [Protocol Appendix J_TICS-M] | 1.0 | 30 September 2021 |
| Other [Protocol Appendix K-short ZDS] | 1.0 | 30 September 2021 |
| Other [Delegation Log of site responsibility] | 1.0 | 30 September 2021 |
| Other [full protocol with tracked changes] | 2.0 | 02 December 2021 |
| Other [Participant re-consent, tracked changes] | 2.0 | 02 December 2021 |
| Other [Participant re-consent,clean] | 2.0 | 02 December 2021 |
| Other [PIS Consultee, tracked changes] | 2.0 | 02 December 2021 |
| Other [Consultee PIS, clean] | 2.0 | 02 December 2021 |
| Other [Consultee by telephone, tracked] | 2.0 | 02 December 2021 |
| Other [consultee telephone declaration, clean] | 2.0 | 02 December 2021 |
| Other [Consultee declaration, tracked changes] | 2.0 | 02 December 2021 |
| Other [consultee declaration, clean] | 2.0 | 02 December 2021 |
| Other [Protocol Appendix B_FOIS] | 1.0 | 30 September 2021 |
| Other [2nd cover letter toREC with responses] | NA | 02 December 2021 |
| Participant consent form [Participant consent, tracked changes] | 2.0 | 02 December 2021 |
| Participant consent form [Participant consent, clean] | 2.0 | 02 December 2021 |
| Participant consent form [PIS/consent combined short pictorial, tracked changes] | 2.0 | 02 December 2021 |
| Participant consent form [PIS/consent combined short pictorial, clean] | 2.0 | 02 December 2021 |
| Participant information sheet (PIS) [PIS long version, tracked changes] | 2.0 | 02 December 2021 |
| Participant information sheet (PIS) [PIS long version, clean] | 2.0 | 02 December 2021 |
| Research protocol or project proposal [Full protocol, clean version] | 2.0 | 02 December 2021 |
| Summary CV for Chief Investigator (CI) [Chief Investigator CV] | | 23 March 2020 |

**Membership of the Committee**

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**User Feedback**

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

**HRA Learning**

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

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|---|---|
| **IRAS project ID: 304658** | **Please quote this number on all correspondence** |

With the Committee's best wishes for the success of this project.

Yours sincerely

PP

Tracy Hamrang

**Dr Niki Bannister**
**Chair**

E-mail: Essex.REC@hra.nhs.uk

Enclosures: List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to: Ms Angela Shone

Lead Nation England: approvals@hra.nhs.uk

**East of England - Essex Research Ethics Committee**

**Attendance at Committee meeting on 04 November 2021**

## Committee Members:

| *Name* | *Profession* | *Present* | *Notes* |
|---|---|---|---|
| Mrs Janice Allen | Retired Assistant Head of Governance Services | Yes | |
| Miss Aimee Bambury | Senior ethics and compliance specialist | No | |
| Dr Niki Bannister (Chair) | Retired Hospital Doctor | Yes | |
| Miss Suzanne Cross | Retired Deputy Corporate Secretary | Yes | |
| Dr Gerry Kamstra | Retired Solicitor | Yes | |
| Dr Paul Kiff | Director of the Research Advice Service | No | |
| Dr Katharine Nelson | Veterinary Surgeon | Yes | |
| Dr Susan Smith | Research Adviser | No | |
| Ms Sarah Starr | Senior Nurse | Yes | |
| Dr Andy Stevens | Media Consultant & Retired Principal Lecturer | Yes | |
| Mr Michael Tydeman | Retired Consultant in Drug Development | Yes | |
| Dr Nkiruka Umaru | Pharmacist | Yes | |

## Also in attendance:

| *Name* | *Position (or reason for attending)* |
|---|---|
| Ms Tracy Hamrang | Approvals Administrator |
| Vic Strutt | Approvals Specialist |