

## Scotland A Research Ethics Committee

## South East Scotland Research Ethics Service

2nd Floor Waverley Gate  
2-4 Waterloo Place  
Edinburgh  
EH1 3EG  
E-Mail: [sesres@nhslothian.scot.nhs.uk](mailto:sesres@nhslothian.scot.nhs.uk)  
[www.hra.nhs.uk](http://www.hra.nhs.uk)

Enquiries to: Eilidh Clifford  
E-Mail: [eilidh.clifford@nhslothian.scot.nhs.uk](mailto:eilidh.clifford@nhslothian.scot.nhs.uk)

24 November 2022

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

Dear Professor Bath,

**Study title:** Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)  
**REC reference:** 21/SS/0075/AM02  
**Protocol number:** 21068  
**Amendment number:** SA\_05\_22  
**Amendment date:** 27 October 2022  
**IRAS project ID:** 306761

The above amendment was reviewed by the Sub-Committee in correspondence.

### Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Sub-Committee had no ethical concerns regarding the amendment.

### Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [306761_SA_05_22_]	1.6	27 October 2022
GP/consultant information sheets or letters [PhEAST GP letter v3.0 20221027_clean]	3.0	27 October 2022
GP/consultant information sheets or letters [PhEAST GP letter v3.0 20221027_trackedchanges]	3.0	27 October 2022

Chair-Dr Mary-Joan MacLeod

Participant consent form [PhEAST Scotland Informant (WA.WG.NR) Consent Form_Final v1.0 20220624]	1.0	24 June 2022
Participant information sheet (PIS) [PhEAST (Scot) long PIS v5.0 20221027_clean]	5.0	27 October 2022
Participant information sheet (PIS) [PhEAST (Scot) long PIS v5.0 20221027_trackedchanges]	5.0	27 October 2022
Participant information sheet (PIS) [PhEAST (Scot) Participant Recovered Capacity (re-consent) PIS v3.0 20221027_clea]	3.0	27 October 2022
Participant information sheet (PIS) [PhEAST (Scot) Participant Recovered Capacity (re-consent) PIS v3.0 20221027_trackedchanges]	3.0	27 October 2022
Participant information sheet (PIS) [PhEAST Aphasia Friendly PIS and ICF (Scot) V2.0 20221027_clean]	2.0	27 October 2022
Participant information sheet (PIS) [PhEAST Aphasia Friendly PIS and ICF (Scot) V2.0 20221027_trackedchanges]	2.0	27 October 2022
Participant information sheet (PIS) [PhEAST Scotland Legal rep (WA.WG.NR) Information Sheet Final v5.0 20221027_clean]	5.0	27 October 2022
Participant information sheet (PIS) [PhEAST Scotland Legal rep (WA.WG.NR) Information Sheet Final v5.0 20221027_trackedchanges]	5.0	27 October 2022

### Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

### Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

### Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. 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 have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

### Statement of compliance

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.

### 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/>

**IRAS Project ID - 306761:**

**Please quote this number on all correspondence**

Yours sincerely,



**Dr Jill Bradshaw**  
**Chair**

E-mail: [Eilidh.clifford@nhslothian.scot.nhs.uk](mailto:Eilidh.clifford@nhslothian.scot.nhs.uk)

*Enclosures: List of names and professions of members who took part in the review*

*Copy to: Prof Philip Bath, University of Nottingham  
Mrs Angela Shone*

**Scotland A: Adults with Incapacity only**

**Attendance at Sub-Committee of the REC meeting on 11 November 2022**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Jill Bradshaw	Reader in Intellectual and Developmental Disability	Yes	In the Chair
Ms Joanne Mair	Project Manager/Trial Manager	Yes	
Dr Anthony Pottage	Retired Physician/Clinical Pharmacologist	Yes	

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Manx Neill	Scotland A/B REC Manager
Miss Eilidh Clifford	REC Assistant