

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

Enquiries to: Sriparna.Pal
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08 September 2022

Professor Philip Bath
Professor of Stroke Medicine
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
Protocol number: 21068
Amendment number: SA_03_22
Amendment date: 08 August 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.

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_03_22_]	1.6	08 August 2022
Participant consent form [PhEAST (Scot) Participant consent final v3.0 20220513_clean]	3.0	13 May 2022
Participant consent form [PhEAST (Scot) Participant consent final v3.0 20220513_trackedchanges]	3.0	13 May 2022
Participant consent form [PhEAST Scotland Informant (WA.WG.NR) Tel Consent Form V1.0 20220624]	1.0	24 June 2022
Participant consent form [PhEAST Scotland Legal Rep (WA.WG.NR) Consent Form_Final v4.0 20220513_clean]	4.0	13 May 2022

Participant consent form [PhEAST Scotland Legal Rep (WA.WG.NR) Consent Form_Final v4.0 20220513_trackedchanges]	4.0	13 May 2022
Participant consent form [PhEAST Scotland Legal Rep (WA.WG.NR) Tel Consent Form v4.0 20220513_clean]	4.0	13 May 2022
Participant consent form [PhEAST Scotland Participant Recovered Capacity Re-consent Final v4.0 20220513_clean]	4.0	13 May 2022
Participant consent form [PhEAST Scotland Participant Recovered Capacity Re-consent Final v4.0 20220513_trackedchanges]	4.0	13 May 2022
Participant information sheet (PIS) [PhEAST (Scot) long PIS v4.0 20220513_clean]	4.0	13 May 2022
Participant information sheet (PIS) [PhEAST (Scot) long PIS v4.0 20220513_trackedchanges]	4.0	13 May 2022
Participant information sheet (PIS) [PhEAST (Scot) Participant Recovered Capacity (re-consent) PIS v2.0 20220513_clean]	2.0	13 May 2022
Participant information sheet (PIS) [PhEAST (Scot) Participant Recovered Capacity (re-consent) PIS v2.0 20220513_trackedchanges]	2.0	13 May 2022
Participant information sheet (PIS) [PhEAST Aphasia Friendly PIS and ICF V1.0 20220629]	1.0	29 June 2022
Participant information sheet (PIS) [PhEAST Scotland Informant (WA.WG.NR) Information Sheet Final v1.020220624_clean]	1.0	24 June 2022
Participant information sheet (PIS) [PhEAST Scotland Legal rep (WA.WG.NR) Information Sheet Final v4.0 20220513_clean]	4.0	13 May 2022
Participant information sheet (PIS) [PhEAST Scotland Legal rep (WA.WG.NR) Information Sheet Final v4.0 20220513_trackedchanges]	4.0	13 May 2022
Participant information sheet (PIS) [PhEAST Scotland Legal Rep (WA.WG.NR) Tel Consent Form v4.0 20220513_trackedchanges]	4.0	13 May 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 Mary-Joan Macleod
Chair

E-mail: Manx.Neill@nhslothian.scot.nhs.uk

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

Copy to: Mrs Angela Shone

Scotland A: Adults with Incapacity only

Attendance at Sub-Committee of the REC meeting on 30 August 2022

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Mary-Joan Macleod	Clinical Pharmacologist/Consultant Physician	Yes	
Dr Anthony Pottage	Retired Physician/Clinical Pharmacologist	Yes	
Dr Charles Wallis	Consultant in Anaesthesia & Intensive Care	Yes	

Also in attendance:

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