



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 the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

20 October 2022

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
Amendment number:	SA_04_22
Amendment date:	15 September 2022
IRAS project ID:	304658

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 [304658_SA_04_22_]	1.6	15 September 2022
Confirmation of any other Regulatory Approvals (e.g. CAG) and all correspondence [IRAS 304658_SA_04_22_Radiation_Assurance_Research_Exposure_Form_MPE CRE 07-09-2022]	2.1	11 June 2020
Other [FullDatasetTrialForm]	6.3.2	15 September 2022
Other [updated IRAS form]		12 September 2022
Participant information sheet (PIS) [PhEAST Aphasia Friendly PIS and ICF V2.0 20220809_clean]	2.0	09 August 2022
Participant information sheet (PIS) [PhEAST Aphasia Friendly PIS and ICF V2.0 20220809_trackedchanges]	2.0	09 August 2022
Participant information sheet (PIS) [PhEAST Consultee PIS Final V4.0 20220809_clean]	4.0	09 August 2022
Participant information sheet (PIS) [PhEAST Consultee PIS Final V4.0 20220809_trackedchanges]	4.0	09 August 2022
Participant information sheet (PIS) [PhEAST long PIS Final V4.0 20220809_clean]	4.0	09 August 2022
Participant information sheet (PIS) [PhEAST long PIS Final V4.0 20220809_trackedchanges]	4.0	09 August 2022
Research protocol or project proposal [PhEAST Protocol Final clean]	5	09 August 2022
Research protocol or project proposal [PhEAST Protocol Final Tracked Changes]	5	09 August 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 - 304658:

Please quote this number on all correspondence

Yours sincerely



PP
Dr Gerry Kamstra
Chair

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

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

Copy to: Ms Angela Shone

East of England - Essex Research Ethics Committee

Attendance at Sub-Committee of the REC meeting held in correspondence.

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Gerry Kamstra (Chair)	Retired Solicitor	Yes	
Dr Nkiruka Umaru	Pharmacist	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Tracy Hamrang	Approvals Administrator