

East of England - Essex Research Ethics Committee

2 Redman Place
London
EC20 1 JQ

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.

31 May 2024

Prof Philip Bath
University of Nottingham
Stroke Trials Unit, Mental Health & Clinical Neurosciences
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_10_24
Amendment date: 08 May 2024
IRAS project ID: 304658

The above amendment was reviewed on 28 May 2024 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 [SA_10_24 Completed amendment tool]	1.6	08 May 2024

Other [Treatment Tick-List for Participant]	1.0	16 April 2024
Other [Communication Aid For Use During Treatment]	1.0	16 April 2024
Other [Aphasia friendly participant information on PES treatment (updated received by email)]	1	16 April 2024
Other [PES treatment guide for participants]		
Other [Response to REC amendment queries]	n/a	n/a
Research protocol or project proposal [PhEAST Protocol v10.0 (tracked-changes)]	10.0	08 May 2024
Research protocol or project proposal [PhEAST Protocol v10.0 (clean)]	10.0	08 May 2024

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
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Yours sincerely

pp. 

Dr Niki Bannister
Chair

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

Enclosures:

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

East of England - Essex Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 28 May 2024, via correspondence.

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Niki Bannister	Retired Hospital Doctor	Yes	Chair of the REC
Dr Susan Smith	Methods Advisor	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Richard Reed	