

East of England - Essex Research Ethics Committee

2 Redman Place
London
EC20 1 JQ

14 November 2023

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_08_23
Amendment date: 05 October 2023
IRAS project ID: 304658

The above amendment was reviewed at the meeting of the Sub-Committee held on 13 November 2023 via 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_08_23 Locked Amendment Tool]	1.6	05 October 2023
Research protocol or project proposal [Protocol (tracked-changes)]	8.0	15 October 2023

Research protocol or project proposal [Protocol - clean version (received by email)]	8.0	15 October 2023
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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.



Miss Suzanne Cross
Chair

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

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

Copy to: Mr Ali Alshukry

East of England - Essex Research Ethics Committee

**Attendance at Sub-Committee of the REC meeting
on 13 November 2023 via correspondence**

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Miss Rani Badhan	Clinical Trials Project Manager & Senior Trial Practitioner	Yes	
Miss Suzanne Cross (Chair)	Retired Deputy Corporate Secretary	Yes	

Also in attendance:

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