

East of England - Essex Research Ethics Committee

2 Redman Place London EC20 1 JQ

05 December 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_09_23

Amendment date: 21 November 2023

IRAS project ID: 304658

The above amendment was reviewed at the meeting of the Sub-Committee held on 04 December 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:

Document	Version	Date
Completed Amendment Tool [SA_09_23 Amendment tool]	1.6	21 November 2023
Research protocol or project proposal [PhEAST Protocol v9.0 (tracked-changes)]	9.0	21 November 2023
Research protocol or project proposal [PhEAST Protocol v9.0 (clean)]	9.0	21 November 2023

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.

(Richard Reed)

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

Copy to: Mr Ali Alshukry

East of England - Essex Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 04 December 2023 via correspondence

Committee Members:

Name	Profession	Present	Notes
Dr Niki Bannister (Chair)	Retired Hospital Doctor	Yes	
Dr Mark Whiting	Consultant Nurse, Children's Specialist Services	Yes	

Also in attendance:

Name	Position (or reason for attending)
Ms Ana Duarte (observing only)	Clinical Research Practitioner
Mr Richard Reed	Approvals Administrator