

East of England - Essex Research Ethics Committee

Equinox House,
City Link,
Nottingham
NG1 4LA

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.

23 January 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_06_22 |
| Amendment date: | 19 December 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_06_22_] | 1.6 | 19 December 2022 |
| Non-validated questionnaire [PhEAST Postal Follow Up 3, 6, 12 Months v3.0 20230109 clean] | 3 | 09 January 2023 |
| Non-validated questionnaire [PhEAST Postal Follow Up 3, 6, 12 Months v3.0 20230109 tracked changes] | 3 | 09 January 2023 |
| Participant consent form [PhEAST Informant Consent Form V3.0 20221219_trackedchanges] | 3.0 | 19 December 2022 |
| Participant consent form [PhEAST Informant Consent Form V3.0 20221219_clean] | 3.0 | 19 December 2022 |
| Participant consent form [PhEAST Informant Tel Consent Form_England and Wales V3.0 20221912_trackedchanges] | 3.0 | 19 December 2022 |
| Participant consent form [PhEAST Informant Tel Consent Form_England and Wales V3.0 20221912_clean] | 3.0 | 19 December 2022 |
| Participant information sheet (PIS) [PhEAST Consultee PIS Final V5.0 20221219_trackedchanges] | 5.0 | 19 December 2022 |
| Participant information sheet (PIS) [PhEAST Consultee PIS Final V5.0 20221219_clean] | 5.0 | 19 December 2022 |
| Research protocol or project proposal [PhEAST Protocol Appendix M_Cognition Sub Study Scales V2.0 20221219_trackedchanges] | 2.0 | 19 December 2022 |
| Research protocol or project proposal [PhEAST Protocol Appendix M_Cognition Sub Study Scales V2.0 20221219_clean] | 2.0 | 19 December 2022 |
| Research protocol or project proposal [PhEAST Protocol Final V6.0 20221219.docx-trackedchanges] | 6.0 | 19 December 2022 |
| Research protocol or project proposal [PhEAST Protocol Final V6.0 20221219.docx_clean] | 6.0 | 19 December 2022 |
| Validated questionnaire [PhEAST Informant Postal Follow Up 3, 6, 12 Months v1.0 20221219] | 1.0 | 19 December 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 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: 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 Niki Bannister (Chair) | Retired Hospital Doctor | Yes | |
| Dr Katharine Nelson | Veterinary Surgeon | Yes | |

Also in attendance:

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