Scotland A Research Ethics Committee

Research Ethics Service

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Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

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09 February 2022

Professor 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 Professor Bath,

Study title:	**Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)**
REC reference:	**21/SS/0075**
Protocol number:	**21068**
IRAS project ID:	**306761**

Thank you for your letter responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair and Lead & Second Reviewers.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation [as revised], subject to the conditions specified below.

Adults with Incapacity (Scotland) Act 2000

I confirm that the Committee has approved this research project for the purposes of the Adults with Incapacity (Scotland) Act 2000. The Committee is satisfied that the requirements of section 51 of the Act will be met in relation to research carried out as part of this project on, or in relation to, a person who lacks capacity to consent to taking part in the project.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

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 haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Cover letter]		08 October 2021
Covering letter on headed paper [Cover letter]		04 January 2022
Covering letter on headed paper [Cover letter]		04 February 2022
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [sponsor insurance]		26 July 2021
GP/consultant information sheets or letters [letter to GP]	2.0	04 January 2022

IRAS Application Form [IRAS_Form_04102021]		04 October 2021
Letter from funder [NIHR funding letter]		29 July 2021
Letter from sponsor [sponsor letter]		04 October 2021
Organisation Information Document [OID]	1-6	30 September 2021
Other [Delegation log of site responsibility]	1.0	
Other [Validated questionnaire_Appendix B_FOIS]	1.0	30 September 2021
Other [Validated questionnaire_Appendix C-EAT-10]	1.0	30 September 2021
Other [Validated questionnaire_Appendix D_FSS]	1.0	30 September 2021
Other [Validated questionnaire_Appendix E_NIHSS]	1.0	30 September 2021
Other [Validated questionnaire_Appendix F_GCS]	1.0	30 September 2021
Other [Validated questionnaire_Appendix G-EuroQol]	1.0	30 September 2021
Other [Validated questionnaire_Appendix H-mRs]	1.0	30 September 2021
Other [Validated questionnaire_Appendix I_Barthel Index]	1.0	30 September 2021
Other [Validated questionnaire_Appendix J TICS-M]	1.0	30 September 2021
Other [Validated questionnaire_Appendix K-short ZDS]	1.0	30 September 2021
Other [participant re-consent]	3.0	04 February 2022
Other [participant re-consent tracked changes]	3.0	04 February 2022
Other [Legal rep PIS]	3.0	04 February 2022
Other [Legal rep PIS tracked changes]	3.0	04 February 2022
Other [Legal rep consent]	3.0	04 February 2022
Other [Legal rep consent tracked changes]	3.0	04 February 2022
Other [Legal rep telephone consent]	3.0	04 February 2022
Other [Legal Rep telephone consent tracked changes]	3.0	04 February 2022
Other [participant long PIS]	3.0	04 February 2022
Other [participant long PIS tracked changes]	3.0	04 February 2022
Other [participant recovered capacity PIS]	1.0	04 February 2022
Other [participant recovered capacity PIS tracked changes]	1.0	04 February 2022
Participant consent form [participant consent]	2.0	04 January 2022
Participant consent form [participant consent tracked changes]	2.0	04 January 2022
Participant information sheet (PIS) [PIS/consent short pictorial]	2.0	04 January 2022
Participant information sheet (PIS) [PIS/consent short pictorial with tracked changes]	2.0	04 January 2022
Research protocol or project proposal [PhEAST Research Protocol]	1.0	30 September 2021
Schedule of Events or SoECAT [SoECAT]		11 March 2020
Summary CV for Chief Investigator (CI) [Chief investigator CV]		20 March 2020
Validated questionnaire [Protocol Appendix A_DSRS]		30 September 2021

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.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

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: 306761 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

Dr Mary-Joan Macleod
Chair

Email: Manx.Neill@nhslothian.scot.nhs.uk

Enclosures: "After ethical review – guidance for researchers" *[SL-AR2]*

Copy to: Mrs Angela Shone
Lead Nation: England: approvals@hra.nhs.uk