Prof Philip Bath
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07 January 2022

Dear Prof Bath

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Pharyngeal Electrical stimulation for Acute Stroke dysphagia Trial (PhEAST)**
IRAS project ID:	**304658**
Protocol number:	**21068**
REC reference:	**21/EE/0252**
Sponsor	**University of Nottingham**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **304658**. Please quote this on all correspondence.

Yours sincerely,
Vic Strutt

Approvals Specialist

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

Copy to: *Ms Angela Shone*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement template	4.3	01 March 2021
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [sponsor insurance]		26 July 2021
GP/consultant information sheets or letters [letter to GP, clean]	2.0	02 December 2021
IRAS Application Form [IRAS_Form_04102021]		04 October 2021
IRAS Checklist XML [Checklist_04102021]		04 October 2021
Letter from funder [NIHR funding]		29 July 2021
Letter from sponsor [sponsor letter]		04 October 2021
Organisation Information Document [OID]	0.1	30 September 2021
Other [consultee declaration, clean]	2.0	02 December 2021
Other [Protocol Appendix B_FOIS]	1.0	30 September 2021
Other [2nd cover letter toREC with responses]	NA	02 December 2021
Other [Protocol Appendix A_DSRS]	1.0	30 September 2021
Other [Protocol Appendix C_EAT-10]	1.0	30 September 2021
Other [Protocol Appendix D_FSS]	1.0	30 September 2021
Other [Protocol Appendix E_NIHSS]	1.0	30 September 2021
Other [Protocol Appendix F_GCS]	1.0	30 September 2021
Other [Protocol Appendix G_EuroQoL]	1.0	30 September 2021
Other [Protocol Appendix H_mRs]	1.0	30 September 2021
Other [Protocol Appendix I_Barthel]	1.0	30 September 2021
Other [Protocol Appendix J_TICS-M]	1.0	30 September 2021
Other [Protocol Appendix K-short ZDS]	1.0	30 September 2021
Other [Delegation Log of site responsibility]	1.0	30 September 2021
Other [full protocol with tracked changes]	2.0	02 December 2021
Other [Participant re-consent,clean]	2.0	02 December 2021
Other [Consultee PIS, clean]	2.0	02 December 2021
Other [Consultee by telephone, tracked]	2.0	02 December 2021
Other [consultee telephone declaration, clean]	2.0	02 December 2021
Participant consent form [Participant consent, clean]	2.0	02 December 2021
Participant consent form [PIS/consent combined short pictorial, clean]	2.0	02 December 2021
Participant information sheet (PIS) [PIS long version, clean]	2.0	02 December 2021
Research protocol or project proposal [Full protocol, clean version]	2.0	02 December 2021
Schedule of Events or SoECAT [SoECAT]	1.19	11 March 2020
Summary CV for Chief Investigator (CI) [Chief Investigator CV]		23 March 2020

IRAS project ID	304658

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
All sites will perform the same research activities therefore there is only one site type.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study.	An Organisation Information Document has been submitted and the sponsor is intending to use a separate site agreement. The agreement has been modified as follows: The front page amended to include additional identifiers and logo.Study drug redefined in the definitions as Investigational	Study funding will be provided to site as per the SoECAT.	A Principal Investigator should be appointed at study sites.	No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, network staff (or similar) undertaking any of the research activities listed in the IRAS form (except for administration of questionnaires or surveys), would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university employed) or an NHS to NHS confirmation of pre-engagement

		Medicinal Product so that this is not misinterpreted when a drug is used in a non-CTIMP.Clauses 3.9 – 3.12 removed as they can never be applicable when the University is the sponsor. Clauses 3.13 and 3.14 have been renumbered 3.8 and 3.9 accordingly.Clause 6.1 amended to include that the CI can provide permission on behalf of the sponsor.Clause 16.5 amended to state that the agreement can only be executed in counterpart where it is not a CTIMP.Formatting			checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For research team members only administering questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate.

		changes made to reduce the number of pages.These changes are provided by the sponsor and the HRA and HCRW take no position on the acceptability of these changes. Participating NHS organisations should now determine its acceptability and liaise with the sponsor to confirm the content of the agreement.			

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.