Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Dr Jacqueline Benfield
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Royal Derby Hospital
Uttoxeter Road
Derby
DE22 3NE

Email: approvals@hra.nhs.uk

12 June 2023

Dear Dr Benfield,

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

Study title:	**SWALLOW STRENGTH AND SKILL TRAINING WITH BIOFEEDBACK IN ACUTE POST STROKE DYSPHAGIA**
IRAS project ID:	**319969**
Protocol number:	**22043**
REC reference:	**23/LO/0131**
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 **319969**. Please quote this on all correspondence.

Yours sincerely,
Chris King

Approvals Specialist

Email: **INSERT for nation of sender** approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

Copy to: *Ms Angela Shone, Sponsor's Representative*

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 [Non commercial Agreement template]		31 January 2023
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Indemnity Insurance]		
Interview schedules or topic guides for participants [Clinician Interview Topic Guide]	Final Version 1.0	03 November 2022
IRAS Application Form [IRAS_Form_25012023]		25 January 2023
Letter from sponsor [22043 Sponsor Letter HRA REC]	3.0	
Organisation Information Document [Organisation Information Document]		
Other [Videofluoroscopy assessment protocol]	Final Version 1.0	03 November 2022
Other [Participant Diary]	Final Version 1.0	03 November 2022
Other [Baseline outcome measures 'questionnaire']	Final Version 1.0	24 January 2023
Other [Day 15 outcome measures 'questionnaire']	Final Version 1.0	24 January 2023
Other [Day 90 outcome measure 'questionnaire']	Final Version 1.0	24 January 2023
Other [Participant Information Sheet (+VFS)]	Final Version 1.1	28 February 2023
Other [Consultee Information Sheet (+VFS)]	Final Version 2.1	28 February 2023
Other [Consent form (+VFS)]	Final Version 1.1	02 March 2023
Other [Advice consent form (+VFS)]	Final Version 2.1	01 March 2023
Other [Master Delegation Log]		03 November 2022
Other [Professional Indemnity Insurance]		
Participant consent form [Consent form]	Final Version 1.1	02 March 2023
Participant consent form [Consultee advice form]	Final Version 2.1	02 March 2023
Participant consent form [Clinician Interview Consent form]	Final Version 1.1	02 March 2023
Participant consent form [Clinician Observation Consent form]	Final Version 1.1	02 March 2023
Participant information sheet (PIS) [Participant Information Sheet]	Final Version 1.1	27 February 2023
Participant information sheet (PIS) [Aphasia Friendly Participant Information Sheet]	Final Version 1.1	02 March 2023
Participant information sheet (PIS) [Consultee Information Sheet]	Final Version 1.1	28 February 2023
Participant information sheet (PIS) [Clinician Interview Information sheet]	Final Version 1.1	28 February 2023
Participant information sheet (PIS) [Clinician Observation Information sheet]	Final Version 1.1	02 March 2023
Participant information sheet (PIS) [Aphasia Friendly Participant Information Sheet (+VFS)]	2.1	02 June 2023

Research Exposure Form [Radiation Assurance confirmed]		22 December 2022
Research protocol or project proposal [Protocol ssSIP Final Version 1.0 3 November 2022]	Final Version 1.0	03 November 2022
Schedule of Events or SoECAT [SoECAT]	Final Version 1.0	03 November 2022
Summary CV for Chief Investigator (CI) [CV Jacqueline Benfield]		03 November 2022

IRAS project ID	319969

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. The only exception to this is Royal Derby Hospital that will be the only site conducting Videofluoroscopy.	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 in accordance with the contracting expectations detailed.	An Organisation Information Document has been submitted but the sponsor is intending to use a separate agreement with participating NHS organisations of this type. The sponsor has supplied a modified model agreement and intends to use this with participating NHS organisations. The agreement has been modified as follows; • Study drug has been	The sponsor has detailed its proposals with respect to whether any study funding will be provided to participating NHS organisations of this type in the Organisational Information Document and in the **alternative site agreement that they propose to use as the agreement**. These should be read in conjunction with the relevant Schedule of Events/SoECAT which details the cost implications of the study for participating	A Principal Investigator should be appointed at participating NHS organisations.	Where an external individual who does not already hold an NHS employment contract will be conducting any of the research activities that will be undertaken at this site type then they would be expected to hold an Honorary Research Contract. External staff holding pre-existing NHS employment contracts should obtain a Letter of Access.These should confirm Occupational Health Clearance.These should confirm enhanced DBS checks and appropriate barred list checks.

		redefined in the definitions as Investigational Medicinal Product so that this is not misinterpreted when a drug is used in a non-CTIMP. • Clauses 3.9 – 3.12 have been removed as they can never be applicable when the University is the sponsor. Clauses 3.13 and 3.14 have been therefore been renumbered 3.9 and 3.10 accordingly. • Clause 6.1 has been amended to	NHS organisations.		

		include that the CI can provide permission on behalf of the sponsor. These changes are provided by the sponsor and the HRA and HCRW take no position on their acceptability. Participating NHS organisations should now determine the acceptability of the proposed agreement and liaise with the sponsor to confirm its content			

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.