

Emily Stanyard (staff)

From: BB-sponsor
Sent: 16 June 2023 10:38
To: MS-PhEAST
Subject: FW: IRAS Project ID 304658. HRA and HCRW Approval for the Amendment

Categories: ES to respond

From: Essex.REC@hra.nhs.uk <noreply@harp.org.uk>
Sent: 16 June 2023 10:29
To: Philip Bath (staff) <mszpb@exmail.nottingham.ac.uk>; sponsor@nottingham.ac.uk
Subject: IRAS Project ID 304658. HRA and HCRW Approval for the Amendment

Dear Prof Bath,

IRAS Project ID:	304658
Short Study Title:	Pharyngeal Electrical stimulation (PES) for Post Stroke dysphagia (PSD)
Amendment No./Sponsor Ref:	NSA_14_23
Amendment Date:	09 May 2023
Amendment Type:	Non Substantial Non-CTIMP

I am pleased to confirm **HRA and HCRW Approval** for the above referenced amendment.

You should implement this amendment at NHS organisations in England and Wales, in line with the guidance in the amendment tool.

The following information should be provided to participating NHS organisations

The following modifications have been made to the mNCA 2022:

- The front page has been amended to include additional identifiers and logo.
- Study drug has been redefined in the definitions as Investigational Medicinal Product so that this is not misinterpreted when a drug is used in a non-CTIMP.
- The definition of Trial Site has been included in the definitions as the contracting body for the site/s.
- Clauses 3.9 - 3.12 have been removed. Clauses 3.13 and 3.14 have therefore been renumbered 3.9 and 3.10 accordingly.
- Invoice address updated.

Participating NHS organisations should now determine the acceptability of the modifications and liaise with the sponsor to confirm the content of the agreement. Please note, this waiver does not constitute approval of the agreement, nor does it require NHS organisations to use this agreement.

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/>.

Please contact amendments@hra.nhs.uk for any queries relating to the assessment of this amendment.

Kind regards

Benita Hallewell-Goodwin

Health Research Authority

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W. www.hra.nhs.uk

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