Philip Bath
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Email: approvals@hra.nhs.uk

29 August 2025

Dear Philip Bath

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

Study title:	**CerebroVascular Disease-Cognition (CVD-Cog) phase-2 trial in non-lacunar ischaemic stroke with cerebral small vessel disease**
IRAS project ID:	**1011543**
Protocol number:	**25017**
REC reference:	**25/WM/0144**
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 **1011543**. Please quote this on all correspondence.

Yours sincerely,
Vic Strutt

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Philip Bath, University of Nottingham*

List of Documents

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

Document	*Version*	*Date*
Cover Letter [Cover letter]	1.0	24 June 2025
EudraCT PDF [Medicines Information]		20 August 2025
GP/consultant information sheets or letters [GP letter - clean]	1.1	25 July 2025
GP/consultant information sheets or letters [GP letter - tracked]	1.1	25 July 2025
Investigator Brochure/SmPC [SmPC ISMN]	1.0	01 January 2018
Investigator Brochure/SmPC [SmPC ISMN XL]	1.0	09 April 2024
Investigator Brochure/SmPC [SmPC cilostazol]	1.0	09 March 2020
Letter from funder [Funding letter]	1.0	31 January 2025
Letter from sponsor [Sponsor letter]	1.0	24 June 2025
Miscellaneous [Telephone discussion record]	1.0	23 June 2025
Miscellaneous [Drug info sheet ISMN non XL]	1.0	23 June 2025
Miscellaneous [Drug info sheet cilostazol]	1.0	23 June 2025
Miscellaneous [Drug info sheet ISMN XL]	1.0	23 June 2025
Miscellaneous [Drug info sheet ISMN XL & Cilostazol]	1.0	23 June 2025
Miscellaneous [Drug info sheet ISMN & Cilostazol]	1.0	23 June 2025
Miscellaneous [Trial delegation log]	1.0	23 June 2025
Miscellaneous [Lay summary]	1.1	08 July 2025
Miscellaneous [Poster - updated]	1.1	25 July 2025
Miscellaneous [Consent to contact - clean]	1.1	25 July 2025
Miscellaneous [Consent to contact form - tracked]	1.1	25 July 2025
Organisation Information Document [OID]	1.0	23 June 2025
Other [mNCA]	1.0	01 July 2022
Participant information and informed consent form [Participant Informant contact details]	1.0	23 June 2025
Participant information and informed consent form [Informant consent to contact]	1.0	23 June 2025
Participant information and informed consent form [Informant information sheet - tracked]	1.1	25 July 2025
Participant information and informed consent form [Informant information sheet - clean]	1.1	25 July 2025
Participant information and informed consent form [PIS RIS appendices]	1.0	23 June 2025
Participant information and informed consent form [Participant Informed Consent]	1.0	23 June 2025
Participant information and informed consent form [PIS - clean]	1.1	25 July 2025
Participant information and informed consent form [PIS - tracked]	1.1	25 July 2025
Participant information and informed consent form [Legal rep information sheet - tracked]	1.1	25 July 2025
Participant information and informed consent form [Legal rep information sheet - clean]	1.1	25 July 2025
Participant information and informed consent form [Legal rep informed consent - tracked]	1.1	25 July 2025
Participant information and informed consent form [Legal rep informed consent - clean]	1.1	25 July 2025
Participant information and informed consent form [Contraception	1.1	25 July 2025

information sheet - clean]		
Participant information and informed consent form [Contraception information sheet - tracked]	1.1	25 July 2025
Participant information and informed consent form [Combined PIS and consent form - clean]	1.1	25 July 2025
Participant information and informed consent form [Combined PIS and consent form - tracked]	1.1	25 July 2025
Project Information - PDF [ProjectStudyInformation]		20 August 2025
Proof of Insurance [Insurance certificate]	1.0	01 August 2024
Protocol [Protocol - tracked]	1.1	25 July 2025
Protocol [Protocol - clean]	1.1	25 July 2025
Sample diary card/patient card [Patient drug card]	1.0	23 June 2025
Schedule of Events or SoECAT [SoECAT]	1.0	23 June 2025
Suitability of the investigator/Investigator CV [CI CV]	1.0	19 March 2025

IRAS project ID	1011543

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
Research activities and procedures as per the protocol and other study documents will take place at participating NHS organisations.	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. The sponsor has supplied the unmodified model agreement and intends to use this with participating NHS organisations.	Study funding arrangements are detailed in the agreement.	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.

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.