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04 December 2023

Dear Dr England

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

Study title:	**Remote Ischaemic Conditioning After Stroke 3 (RECAST-3): A multicentre randomised controlled trial**
IRAS project ID:	**277021**
Protocol number:	**20011**
REC reference:	**20/NW/0173**
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 **277021**. Please quote this on all correspondence.

Yours sincerely,

Rekha Keshvara

Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *Mr Ali Alshukry*

List of Documents

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

Document	Filename	Version	Date
IRAS	Updated IRAS Form		03 November 2021
Technical Dossier	995104 – Iss 01 – Product Training Guidance – AT4 Electronic Tourniquet – RECAST-3	01	11 October 2023
Schedule of Events or SoECAT	RECAST-3 SoECAT – Signed 11 Oct 2023 amended end date	1.19	11 October 2023
Consultee advice form	RECAST-3 England Consultee Declaration Form	3.0	05 September 2023
Consent form	RECAST-3 England Consent form	3.0	05 September 2023
Participant information and informed consent form	RECAST-3 Consultee Information Sheet	3.0	05 September 2023
GP/consultant information sheets or letters	RECAST-3 England GP letter	2.0	05 September 2023
Consent form	RECAST-3 England PIS Re-consent	3.0	05 September 2023
Participant information and informed consent form	RECAST-3 England PIS	3.0	05 September 2023
GP/consultant information sheets or letters	RECAST-3 Day 90 GP postal letter	1.0	05 September 2023
GP/consultant information sheets or letters	RECAST-3 Practice Manager Letter	1.0	05 September 2023
Protocol	RECAST-3 Protocol	4.0	04 August 2023
Participant information and informed consent form	RECAST-3 Telephone Consent Record	2.0	05 September 2023
Validated questionnaire	ReCAST-3_Day_90_follow-up_20230202_v1.1_postal	1.1	02 February 2023
Miscellaneous	RECAST-3 Device Sticker	1.0	05 September 2023

	mNCA		01 July 2022
Modifications to the mNCA	Modifications to the mNCA	1.0	02 February 2023
REC approval letter	REC approval letter		22 November 2023
Sponsor contact delegation letter	Sponsor contact delegation letter		10 July 2023
	RECAST-3 MRI Consent form	1.0	06 March 2020
	Organisation information document	1.0	
CI CV	T England short CV		21 December 2019

IRAS project ID	277021

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
There will be two site types: Site type one: Where all site activities, including MRI scanning, will take place as per the protocol. Site type two: Where all site activities, except MRI scanning, will take place as per the protocol.	Site types one and two: 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.	Site types one and two: An Organisation Information Document has been submitted and the sponsor is intending to use a separate site agreement. Modifications have been made. See section 3 Liabilities and Indemnity and section 6 Publication. These changes are provided by the sponsor and the	Funding has been secured from the NIHR. .	Site types one and two: A principal investigator is expected at site.	Site types one and two: Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application 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 checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health

		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.			clearance.

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.