

06 December 2023

Dr Tim England
Consultant Stroke Physician
University of Nottingham
Vascular Medicine, Division of Medical Sciences & GEM
The Medical School, Royal Derby Hospital, Uttoxeter Rd,
Derby
DE22 3NE

Dear Dr England,

Study title:	Remote Ischaemic Conditioning After Stroke 3 (RECAST-3): A multicentre randomised controlled trial
REC reference:	20/SS/0047
Protocol number:	20011
Amendment number:	SA/06/23
Amendment date:	12 October 2023
IRAS project ID:	282606

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The Sub-Committee reviewed the amendment and supporting AWI paperwork. The Committee members observed the need to include an independent contact person in the PISs and suggested rephrasing in PISs and Consent forms to allow participants to decide the preferences in case of the capacity loss during the trial.

The Trial Manager responded back with all the updated documents and after further review the Sub-Committee had no further concerns regarding the amendment.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [Locked Amendment Tool]	Template v1.6	12 October 2023
Confirmation of any other Regulatory Approvals (e.g. CAG) and all correspondence [FO Letter-Greater Manchester REC]		22 November 2023
Covering letter on headed paper [Scottish REC Cover Letter]	N/A	05 September 2023
GP/consultant information sheets or letters [Day 90 GP Postal Letter]	1.0	05 September 2023
GP/consultant information sheets or letters [Practice Manager Letter]	1.0	05 September 2023
GP/consultant information sheets or letters [Clean GP Letter]	2.0	05 September 2023
GP/consultant information sheets or letters [Tracked GP Letter]	2.0	05 September 2023
Instructions for use of medical device [995104 - Iss 01 - Product Training Guidance - AT4 Electronic Tourniquet - RECAST-3]	01	11 October 2023
Other [Device Sticker]	1.0	05 September 2023
Other [Clean Welfare Attorney Consent Form]	3.0	05 September 2023
Other [Tracked Welfare Attorney Consent Form]	3.0	05 September 2023
Other [ReCAST-3_Day_90_follow-up_20230202_v1.1_postal]	1.1	02 February 2023
Other [Sponsor contact delegation letter]	N/A	10 July 2023
Participant consent form [RECAST-3 Scotland Consent Form Final Version V3.0 20231130 CIn]	3.0	30 November 2023
Participant consent form [RECAST-3 Scotland Consent Form Final Version V3.0 20231130 TC]	3.0	30 November 2023
Participant consent form [Clean Telephone Consent Record]	2.0	05 September 2023
Participant consent form [Tracked Telephone Consent Record]	2.0	05 September 2023
Participant information sheet (PIS) [Tracked PIS Re-consent]	3.0	05 September 2023

Participant information sheet (PIS) [RECAST-3 Scotland PIS Final Version V4.0 20231206 CIn]	4.0	06 December 2023
Participant information sheet (PIS) [RECAST-3 Scotland PIS Final Version V4.0 20231206 TC]	4.0	06 December 2023
Participant information sheet (PIS) [RECAST-3 Scotland PIS Re-consent Final Version V4.0 20231206 CIn]	4.0	06 December 2023
Participant information sheet (PIS) [RECAST-3 Scotland PIS Re-consent Final Version V4.0 20231206 TC]	4.0	06 December 2023
Participant information sheet (PIS) [RECAST-3 Scotland Welfare Attorney Information Sheet Final Version V4.0 20231206 CIn]	4.0	06 December 2023
Participant information sheet (PIS) [RECAST-3 Scotland Welfare Attorney Information Sheet Final Version V4.0 20231206 TC]	4.0	06 December 2023
Research protocol or project proposal [Clean Protocol]	4.0	04 August 2023
Research protocol or project proposal [Tracked Protocol]	4.0	04 August 2023

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance


The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

IRAS Project ID - 282606:	Please quote this number on all correspondence
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Yours sincerely,



Professor Jill Bradshaw
Chair

E-mail: Sriparna.Pal@nhslothian.scot.nhs.uk

Enclosures: List of names and professions of members who took part in the review

Copy to: Mrs Angela Shone

Scotland A: Adults with Incapacity only

Attendance at Sub-Committee of the REC meeting on 02 November 2023

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Professor Jill Bradshaw	Professor of Communication in Intellectual and Developmental Disabilities/Consultant Speech & Language Therapist	Yes	
Mrs Anne Forster	Retired Product Development Manager (Standard Life)	Yes	
Dr Maria Truesdale	Senior Lecturer in Intellectual Disabilities	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Manx Neill	Scotland A/B REC Manager
Mrs Sriparna Pal	Administrative Assistant-Scotland A REC