Mr Sandip Nandhra
NIHR Academic Clinical Lecturer
Northern Vascular Centre
Level 4, Freeman Hospital
Newcastle
NE77DN

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

04 August 2021

Dear Mr Nandhra

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

| | |
|---|---|
| **Study title:** | **A Multicentre Prospective observational study to investigate the prevalence and short-term impact of frailty in chronic limb threatening ischaemia (CLTI)** |
| **IRAS project ID:** | **294528** |
| **Protocol number:** | **1** |
| **REC reference:** | **21/PR/0750** |
| **Sponsor** | **Newcastle Upon Tyne University Hospitals** |

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 **294528**. Please quote this on all correspondence.

Yours sincerely,

Harriet Wood
Approvals Specialist
Email: approvals@hra.nhs.uk

*Copy to:* *Laura Frisby , Newcastle Joint Research Office*

## 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 [N/a] | | |
| Cover Letter [Response to REC & HRA Queries] | | 08 July 2021 |
| GP/consultant information sheets or letters [GP Letter] | 1.0 | 01 May 2021 |
| IRAS Application Form [IRAS_Form_294528/1497931/37/649] | *Received 21/05/2021 | |
| Letter from funder | | 01 May 2021 |
| Other [Clarification re CT Scans] | | |
| Participant consent form | 1.0 | 01 May 2021 |
| Participant information sheet (PIS) [PIS] | 1.1 | 01 July 2021 |
| Research protocol or project proposal [Protocol] | 2 | 01 July 2021 |
| Research protocol or project proposal [Protocol] | v2.0 | 01 July 2021 |
| Sample diary card/patient card [NEADL] | 1.0 | 01 May 1921 |
| Schedule of Events or SoECAT [HRA Validated] | 1 | 04 August 2021 |
| Summary CV for Chief Investigator (CI) [CV] | | 01 May 2021 |
| Validated questionnaire [QoL] | | |

| IRAS project ID | 294528 |
|---|---|

## 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. | 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. | An Organisation Information Document has been submitted and the sponsor is not requesting and does not expect any other site agreement to be used. | No study funding will be provided to sites as per the Organisation Information Document. | A Principal Investigator should be appointed at study sites. | Where arrangements are not already in place, network staff (or similar) undertaking any of the research activities listed in the IRAS form(except for administration of questionnaires or surveys), 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).<br>These should confirm enhanced DBS checks, including appropriate barred list checks, and occupational health clearance. For research team members only administering questionnaires or surveys, a Letter of Access based on standard DBS checks and occupational health clearance would be appropriate |

**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. |