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06 November 2020

Dear Dr McGregor

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

Study title: Rehabilitation Exercise and psycholoGical support
After covid-19 Infection' (REGAIN): a multi-centre
randomised controlled trial

IRAS project ID: 288362

REC reference: 20/EE/0235

Sponsor UHCW NHS Trust

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 **288362**. Please quote this on all correspondence.

Yours Sincerely,
Beverley Mashegede

Email: approvals@hra.nhs.uk

Copy to: Ms Sharisse Alleyne, Sponsor Contact

List of Documents

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Contract/Study Agreement template [Model_NC_PIC_Agreement_v1-0_June2019 - FINAL]	V1.0	10 September 2020
Copies of advertisement materials for research participants [REGAIN Patient Invitation Flyer]	V1.0	10 September 2020
Covering letter on headed paper [REGAIN Cover Letter]	N/A	11 September 2020
GP/consultant information sheets or letters [REGAIN Baseline GP Letter]	V1.0	10 September 2020
GP/consultant information sheets or letters [REGAIN Follow Up GP Letter]	V1.0	10 September 2020
Interview schedules or topic guides for participants [REGAIN Indicative topics for Interview]	V1.0	09 October 2020
IRAS Application Form [IRAS_Form_11092020]		11 September 2020
IRAS Application Form XML file [IRAS_Form_11092020]		11 September 2020
IRAS Checklist XML [Checklist_19102020]		19 October 2020
Letter from funder		
Letters of invitation to participant [REGAIN Patient invitation letter]	V1.0	10 September 2020
Non-validated questionnaire [REGAIN Baseline Questionnaire]	V1.0	17 September 2020
Non-validated questionnaire [REGAIN 3 month Questionnaire]	V1.0	08 September 2020
Non-validated questionnaire [REGAIN 6 month Questionnaire]	V1.0	08 September 2020
Non-validated questionnaire [REGAIN 12 month Questionnaire]	v	08 September 2020
Non-validated questionnaire [REGAIN Initial Screen Form]	V1.0	10 September 2020
Other [IRAS Resubmission Amendments]	N/A	15 October 2020
Other [REGAIN FullDataSetTrialForm]	V2.0	15 October 2020
Participant consent form [REGAIN Consent Form Feasibility]	V1.0	10 September 2020
Participant consent form [REGAIN Consent Form - Clean]	2.1	29 October 2020
Participant information sheet (PIS) [REGAIN PIS practitioner interview - Clean]	2.1	29 October 2020
Participant information sheet (PIS) [REGAIN PIS - Clean]	2.1	29 October 2020
Participant information sheet (PIS) [REGAIN PIS Feasibility]	V1.0	10 September 2020
Participant information sheet (PIS) [REGAIN Pt Baseline CLMHD Letter]	V1.0	10 September 2020
Research protocol or project proposal [REGAIN Protocol - Clean]	2.1	29 October 2020
Response to Request for Further Information [REC response 2nd review]		
Schedule of Events or SoECAT [20200828 REGAIN SoECAT PIC SITES Validated]	N/A	28 August 2020
Summary CV for Chief Investigator (CI) [Gordon McGregor CV March 19]	N/A	31 March 2019
Validated questionnaire [REGAIN Questionnaire Outcome Measurements]	N/A	07 September 2020

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
Single centre study with PIC involvement.	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.	<p>This is a single site study sponsored by the participating NHS organisation. You should work with your sponsor R&D office to make arrangements to set up the study.</p> <p>The sponsor R&D office will confirm to you when the study can start following issue of HRA and HCRW Approval.</p> <p>PIC activities should not</p>	Funded by National Institute for Health Research.	<p>A PI is expected at the main participating organisation.</p> <p>A Local Collaborator is expected at the PIC.</p>	All study activities will be undertaken by local staff employed by the NHS organisation. Therefore, no honorary research contracts or letters of access are expected for this study.

		commence until a PIC Agreement is in place. HRA and HCRW recommend use of the standard Participating NHS Organisation to PIC agreement available and this has been submitted.			
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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.