Health Research Authority

East of England - Cambridge South Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

06 November 2020

Dr Gordon McGregor
Associate Clinical Professor
University Hospitals Coventry and Warwickshire NHS Trust
Department of Cardio-pulmonary rehabilitation
UHCW
Coventry
CV2 2DX

Dear Dr McGregor

Study title:	**Rehabilitation Exercise and psycholoGical support After covid-19 InfectioN' (REGAIN): a multi-centre randomised controlled trial**
REC reference:	**20/EE/0235**
IRAS project ID:	**288362**

Thank you for your letter of 29 October 2020, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair and a Sub-Committee.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Registration is a legal requirement for clinical trials of investigational medicinal products (CTIMPs), except for phase I trials in healthy volunteers (these must still register as a condition of the REC favourable opinion).

Registration should take place as early as possible and within six weeks of recruiting the first research participant at the latest. Failure to register is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

As set out in the UK Policy Framework, research sponsors are responsible for making information about research publicly available before it starts e.g. by registering the research project on a publicly accessible register. Further guidance on registration is available at:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

You should notify the REC of the registration details. We will audit these as part of the annual progress reporting process.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites listed in the application subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
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
Covering letter on headed paper [REGAIN Cover Letter Resubmission]	N/A	16 October 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
Letter from funder		
Letters of invitation to participant [REGAIN Patient invitation letter]	V1.0	10 September 2020
Non-validated questionnaire [REGAIN Initial Screen Form]	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
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 Practitioner Interview]	V2.0 Tracked Changes	12 October 2020
Participant consent form [REGAIN Consent Form - Clean]	2.1	29 October 2020
Participant consent form [REGAIN Consent Form - TC]	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
Participant information sheet (PIS) [REGAIN PIS practitioner interview - Clean]	2.1	29 October 2020
Participant information sheet (PIS) [REGAIN PIS practitioner interview - TC]	2.1	29 October 2020
Participant information sheet (PIS) [REGAIN PIS - Clean]	2.1	29 October 2020
Participant information sheet (PIS) [REGAIN PIS - TC]	2.1	29 October 2020
Research protocol or project proposal [REGAIN Protocol - Clean]	2.1	29 October 2020
Research protocol or project proposal [REGAIN Protocol - TC]	2.1	29 October 2020
Response to Request for Further Information [REC response 2nd review]		
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

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.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

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: 288362 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

Dr Leslie Gelling
Chair

Email: cambridgesouth.rec@hra.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: Ms Sharisse Alleyne