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24 August 2022

Dear Dr O'Neill

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

Study title:	**Remote multicomponent rehabilitation compared to standard care for survivors of critical illness after hospital discharge: a randomised controlled assessor-blind clinical and cost-effectiveness trial with internal pilot (iRehab).**
IRAS project ID:	**310777**
Protocol number:	**22/0029**
REC reference:	**22/LO/0314**
Sponsor	**Ulster University**

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 **310777**. Please quote this on all correspondence.

Yours sincerely,

Kevin Ahmed

Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *Mr Nick Curry*

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 [iRehab mNCA v1.0]	1.0	30 March 2022
Copies of materials calling attention of potential participants to the research [iRehab Patient Invite Poster v1.0]	1.0	25 March 2022
Covering letter on headed paper [iRehab Cover Letter]	N/A	04 April 2022
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [iRehab Ulster University Insurance]	N/A	01 August 2021
GP/consultant information sheets or letters [iRehab GP Letter v1.0]	1.0	25 March 2022
GP/consultant information sheets or letters [iRehab Consultant Hospital Doctor Letter v1.0]	1.0	25 March 2022
GP/consultant information sheets or letters [iRehab HADS GP Letter v1.0]	1.0	25 March 2022
Interview schedules or topic guides for participants [iRehab Exercise Manual v1.0]	1.0	31 March 2022
Interview schedules or topic guides for participants [iRehab Recovery Pack v1.0]	1.0	31 March 2022
Interview schedules or topic guides for participants [iRehab Other Resources v1.0]	1.0	04 April 2022
Interview schedules or topic guides for participants [iRehab 30Sec STS iRehab Researcher and Participant Instructions v1.0]	1.0	28 February 2022
Interview schedules or topic guides for participants [iRehab Notifications Wordings & Screenshots - Patients v1.0]	1.0	01 April 2022
Interview schedules or topic guides for participants [iRehab_Interview script_Participants_V1.0 12.04.2022]	v1.0	12 April 2022
Interview schedules or topic guides for participants [iRehab_Interview script_Staff_V1.0 12.04.2022]	v1.0	12 April 2022
Interview schedules or topic guides for participants [Questionnaire Poll V2.0 06.05.2022]	V2.0	06 May 2022
IRAS Application Form [IRAS_Form_04042022]		04 April 2022
Letter from funder [NIHR132871 O'Neill contract letter 18.08.2021]	N/A	18 August 2021
Letter from sponsor [iRehab Sponsor Letter Ulster University]	N/A	30 March 2022
Letters of invitation to participant [iRehab Patient Invitation Letter from Sites_V2.0 06.05.2022]	V2.0	06 May 2022
Letters of invitation to participant [iRehab Patient Invitation Letter from Sites_V2.0 06.05.2022Tracked]	V2.0	06 May 2022
Letters of invitation to participant [iRehab Interview Invitation Letter from WCTU v1.0]	1.0	01 April 2022
Letters of invitation to participant [iRehab Interview Invitation Email from WCTU v1.0]	1.0	01 April 2022
Letters of invitation to participant [iRehab Baseline Questionnaire Initial Letter (No Internet) v1.0]	1.0	25 March 2022
Letters of invitation to participant [iRehab Baseline Questionnaire Reminder Letter (No Internet) v1.0]	1.0	25 March 2022
Letters of invitation to participant [iRehab 8-Week Questionnaire Initial Letter (No Internet) v1.0]	1.0	25 March 2022
Letters of invitation to participant [iRehab 8-Week Questionnaire Reminder Letter (No Internet) v1.0]	1.0	25 March 2022
Letters of invitation to participant [iRehab 6-Month Questionnaire Initial Letter (No Internet) v1.0]	1.0	25 March 2022
Letters of invitation to participant [iRehab 6-Month Questionnaire Reminder Letter (No Internet) v1.0]	1.0	25 March 2022

Letters of invitation to participant [iRehab Cover Letter Registered Patients v1.0]	1.0	30 March 2022
Letters of invitation to participant [iRehab Randomisation Confirmation Letter v1.0]	1.0	01 April 2022
Letters of invitation to participant [iRehab Cover Letter Intervention Manual v1.0]	1.0	01 April 2022
Letters of invitation to participant [iRehab Cover Letter Intervention Fitbit v1.0]	1.0	01 April 2022
Organisation Information Document [iRehab OID Non-Commercial v1.0]	1.0	30 March 2022
Other [iRehab_Protocol_v2.0_10.05.2022 Tracked]	V2.0	10 May 2022
Other [iRehab Cover Letter 11.05.2022]	N/A	11 May 2022
Other [NIHR External Peer Review and Response 19.02.2021]	N/A	19 February 2021
Other [Trial review within Ulster University 09.03.2022]	N/A	09 March 2022
Other [iRehab Cover Letter 12.04.2022]	N/A	12 April 2022
Participant consent form [iRehab Consent Form v1.0]	1.0	01 April 2022
Participant consent form [iRehab Consent Form Interview Participant and Team Member v1.0]	1.0	01 April 2022
Participant information sheet (PIS) [iRehab PIL Interview Team Member v1.0]	1.0	01 April 2022
Participant information sheet (PIS) [iRehab_PIL_V2.0_06.05.2022]	V2.0	06 May 2022
Participant information sheet (PIS) [iRehab_PIL_V2.0_06.05.2022Tracked]	V2.0	06 May 2022
Participant information sheet (PIS) [iRehab PIL Interview Participant v1.0]	1.0	01 April 2022
Research protocol or project proposal [iRehab_Protocol_v2.0_10.05.2022]	V2.0	10 May 2022
Schedule of Events or SoECAT [iRehab SoECAT Tool A 20.07.21]	v1.0	20 July 2021
Summary CV for Chief Investigator (CI) [Chief Investigator CV]	N/A	27 February 2022
Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only) [iRehab Ulster University Sponsor Requirements]	N/A	30 March 2022
Validated questionnaire [iRehab Scales V1.0 12.04.2022]	v1.0	12 April 2022
Validated questionnaire [iRehab Baseline Questionnaire v1.0]	1.0	25 March 2022
Validated questionnaire [iRehab 8-week Questionnaire v1.0]	1.0	25 March 2022
Validated questionnaire [iRehab 6-month Questionnaire v1.0]	1.0	25 March 2022

IRAS project ID	310777

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 intending to use a model non-commercial agreement with sites.	Study funding will be provided to sites as per the model Non-Commercial Agreement. It is noted this this study has requested inclusion on the CRN portfolio and incurs Excess Treatment Costs. The researchers have provided an AcoRD specialist authorised SoECAT for the purposes of the ETC processes in England.	A Principal Investigator should be appointed at study sites	No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. 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). 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. The applicant has confirmed that any Fitbits, mobile phones and tablets sent to participants will be sent via WCTU