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17 April 2020

Dear Dr Hewitt

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

Study title:	**COPE Study: COVID-19 in Older PEople - the influence of frailty and multimorbidity on survival. A multicentre, international observational study.**
IRAS project ID:	**281951**
Protocol number:	**SPON1815-20**
REC reference:	**20/HRA/1898**
Sponsor	**Cardiff 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 *"After HRA Approval – guidance for sponsors and investigators"* document on the HRA website gives detailed guidance on reporting expectations for studies with HRA and HCRW Approval, 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 **281951**. Please quote this on all correspondence.

Yours sincerely,

Helen Penistone
Approvals Specialist

Email: approvals@hra.nhs.uk
Telephone: 0207 104 8010

Copy to: *Ms Helen Falconer*

List of Documents

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

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance]	V1	23 March 2020
HRA Schedule of Events	1	17 April 2020
IRAS Application Form [IRAS_Form_14042020]		14 April 2020
Letter from sponsor [Sponsor]	V1	23 March 2020
Organisation Information Document		
Research protocol or project proposal [Protocol]	V1.4	18 March 2020
Summary CV for Chief Investigator (CI) [CV CI]	V1	23 March 2020

IRAS project ID	281951

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
There will be one study site type which will be hospitals providing emergency care. Data will be collected at site. This approval covers participating NHS organisations in England and Wales that are hospital Trusts providing emergency care.	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 external funding has been sought. No funding will be available to sites.	A local principal investigator will be appointed at sites to oversee the research activities.	Data will be collected by members of the direct care team. Therefore, it is not expected that any additional HR arrangements will be necessary.

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 do intend to apply for inclusion on the NIHR CRN Portfolio.