Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Health Research Authority

Joseph Cheriyan
Cambridge University Hospitals NHS Foundation Trust
Hills Road
Cambridge
CB2 0QQ

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

29 May 2020

Dear Joseph Cheriyan

Initial Assessment Letter

Study title:	**mulTi-Arm Therapeutic study in pre-ICu patients admitted with Covid-19 – Experimental drugs and mechanisms**
IRAS project ID:	**283769**
EudraCT number:	**2020-002229-27**
Protocol number:	**TACTIC-E**
REC reference:	**20/WM/0169**
Sponsor	**Cambridge University Hospitals NHS Foundation Trust**

Thank you for your application for HRA and Health and Care Research Wales (HCRW) Approval. I am writing to confirm that you are now able to share the Local Information Pack with participating NHS organisations in England and Wales in order to invite them to arrange of capacity and capability to deliver your study. Please note that **the research should not begin** at any participating NHS organisations in England or Wales until HRA and HCRW Approval is issued.

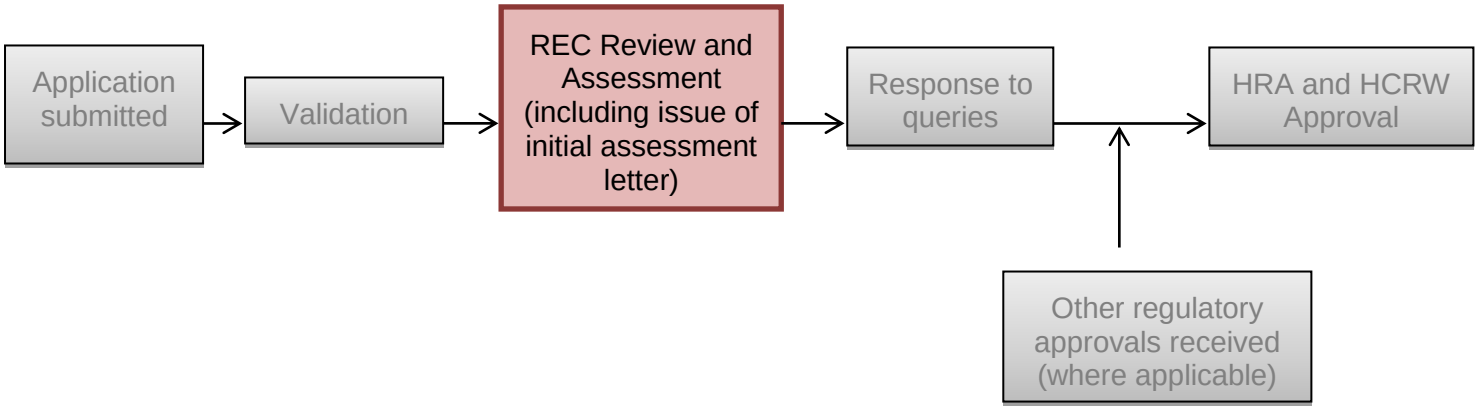
To share the Local Information Pack with participating NHS organisations in England and Wales please use the template email available on the IRAS website.

Once the Local Information Pack has been shared, please work with participating NHS organisations to arrange capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

What happens next with my application for HRA and HCRW Approval?

Your application is progressing. Please find below an indication of where you are in the process (indicated by the red box).

IRAS project ID	283769



I am undertaking the assessment of the application and you will receive any queries following the REC meeting.

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 in Northern Ireland and Scotland.

If you indicated in your IRAS form that you have participating organisations in Northern Ireland and/or Scotland, the national coordinating function of each participating nation has been informed and provided with the initial document set. The relevant national coordinating function/s will contact you as appropriate. We will provide them the final document set and study wide governance report when available.

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.

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 **283769.** Please quote this on all correspondence.

Yours sincerely,

Rekha Keshvara
Approvals Manager

IRAS project ID	**283769**

Email: approvals@hra.nhs.uk

Copy to: *Miss Natalia Igosheva*

Information to support study set up

The below provides all parties with information to support the arranging 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. As part of the application process, details may change prior to a Letter of HRA and HCRW Approval being issued.

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 is one type of participating NHS organisation; activities will be the same at all organisations.	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 separate site agreement. The agreement is unmodified as per the tracked changes. These changes are provided by the sponsor and the HRA and HCRW take no position on	The SoECAT submitted for this study has been authorised by an AcoRD Expert.	A Principal Investigator is expected to be in place at the participating NHS sites.	Use of identifiable patient records held by an NHS organisation to identify potential participants should be undertaken by a member of the direct care team for the patient, so it would not normally be acceptable for this to be done by staff not employed by that organisation. An Honorary Research Contract (or equivalent) would be expected for any external NHS/research staff undertaking all of the other activities for the study once consent from the participant is in place. The pre-engagement checks should include an enhanced DBS check (including a check against the DBS 'barred list' for adults), and

		the acceptability of these changes. Participating NHS organisations should now determine its acceptability and liaise with the sponsor to confirm the content of the agreement.			Occupational Health Clearance.

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.