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

09 June 2020

Dear Joseph Cheriyan

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

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

Yours sincerely,
Rekha Keshvara

Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *Miss Natalia Igosheva*

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		
Copies of advertisement materials for research participants [TACTIC E Poster tracked]	1.1	03 June 2020
Copies of advertisement materials for research participants [TACTIC E Poster clean]	1.1	03 June 2020
Covering letter on headed paper [TACTIC E Cover Letter]		27 May 2020
GP/consultant information sheets or letters [TACTIC E GP letter Ambrisentan + Dapagliflozin]	1.0	27 May 2020
GP/consultant information sheets or letters [TACTIC E GP Letter EDP1815]	1.0	27 May 2020
GP/consultant information sheets or letters [TACTIC E GP Letter SoC]	1.0	27 May 2020
Investigator's brochure / IMP Dossier [TACTIC E EDP1815 IB]	2.1	28 January 2020
IRAS Application Form [IRAS_Form_27052020]		27 May 2020
IRAS Checklist XML [Checklist_27052020]		27 May 2020
Organisation Information Document [TACTIC E OID]	1.0	27 May 2020
Other [TACTIC E Ambrisentan SmPC]		
Other [TACTIC E Legal Representative/Next of Kin PISICF clean]	1.0	03 June 2020
Other [TACTIC E REC response letter]	1.0	04 June 2020
Participant consent form [TACTIC E PISICF]	1.0	27 May 2020
Participant information sheet (PIS) [TACTIC E PISICF Endothelial]	1.0	27 May 2020
Participant information sheet (PIS) [TACTIC E PISICF tracked]	1.1	03 June 2020
Participant information sheet (PIS) [TACTIC E PISICF clean]	1.1	03 June 2020
Participant information sheet (PIS) [TACTIC E Short PISICF tracked]	1.1	03 June 2020
Participant information sheet (PIS) [TACTIC E Short PISICF clean]	1.1	03 June 2020
Referee's report or other scientific critique report [TACTIC E Peer Review John Cockroft]	n/a	
Referee's report or other scientific critique report [TACTIC E Peer Review James Ritter]		
Research protocol or project proposal [TACTIC E Protocol]	1.0	27 May 2020
Sample diary card/patient card [TACTIC E Participant ID card]	1.0	27 May 2020
Schedule of Events or SoECAT [TACTIC E SoECAT]	0.2	26 May 2020
Summary CV for Chief Investigator (CI) [Joseph Cheriyan CV]	n/a	07 April 2020
Summary of product characteristics (SmPC) [TACTIC E Dapagliflozin SmPC]		

IRAS project ID	283769

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 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 acceptability of	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 Occupational Health Clearance.

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

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.