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

26 March 2020

Dear Christopher Butler

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

Study title:	**Platform Randomised trial of INterventions against COVID-19 In older peoPLE**
IRAS project ID:	**281958**
EudraCT number:	**2020-001209-22**
Protocol number:	**PRINCIPLE**
REC reference:	**20/SC/0158**
Sponsor	**University of Oxford / Clinical Trials and Research Governance**

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 **281958**. Please quote this on all correspondence.

Yours sincerely,

Kevin Ahmed
Approvals Manager

Email: approvals@hra.nhs.uk

Copy to: *CTRG*

List of Documents

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

Document	*Version*	*Date*
Confirmation of Clinical Trial Authorisation from MHRA and relevant correspondence [CTA Approval]		26 March 2020
Covering letter on headed paper [Response to REC 25.03.20]		25 March 2020
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UofO Insurance]		
GP/consultant information sheets or letters [PRINCIPLE GP letter 23Mar20 v1]	1	23 March 2020
IRAS Application Form [IRAS_Form_23032020]		23 March 2020
Letter from sponsor [Sponsor Letter]		23 March 2020
Letters of invitation to participant [Test Message Invite]	1.0	24 March 2020
Organisation Information Document	1	23 March 2020
Other [Letter of support_PRINCIPLE trial]		23 March 2020
Other [PHE 8825 Medical Single]		15 August 2018
Other [PHE ISO15189 E certificate for VRD]		09 December 2019
Other [PHE_11571_Throat and Nose self sampling swab instruction sheet 07]		
Other [PRINCIPLE_Baseline_v0.3_22Mar2020]	0.3	22 March 2020
Other [PRINCIPLE_Call CRF_v0.3_22Mar2020]	0.3	22 March 2020
Other [PRINCIPLE_Eligibility_v0.4_22Mar2020]	0.4	22 March 2020
Other [PRINCIPLE_End_of_Follow_Up_Letter_v0.2_23.03.2020]	0.2	23 March 2020
Other [PRINCIPLE_IMP_Label form_v0.4 23.03.20]	0.4	23 March 2020
Other [PRINCIPLE_Participant_Contact_Card_V0.2_19.03.2020]	0.2	19 March 2020
Other [PRINCIPLE_Screening_v0.4_20Mar2020]	0.4	20 March 2020
Other [PRINCIPLE_text message wording_final 0.3 23.03.20]	0.3	23 March 2020
Participant consent form [ICF]	0.5	22 March 2020
Participant information sheet (PIS) [PIS]	v1.0	24 March 2020
Research protocol or project proposal [PRINCIPLE Protocol]	0.12	23 March 2020
Sample diary card/patient card [PRINCIPLE_Daily Diary_v0.4_22Mar2020]	0.4	22 March 2020
Schedule of Events or SoECAT [SoECAT PRINCIPLE_23Mar20_validated]		23 March 2020
Summary CV for Chief Investigator (CI) [Chris Butler CV 2020]		
Summary of product characteristics (SmPC) [SmPC_Plaquenil-Hydroxychloroquine]		

IRAS project ID	281958

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 its own standard agreement with sites.	Study funding will be available to participating sites as per the Organisation Information Document	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.