



Health Research Authority

South Central - Berkshire Research Ethics Committee

Bristol REC Centre
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

26 March 2020

Christopher Butler
University of Oxford
Radcliffe Observatory Quarter, Woodstock Road
Oxford
OX2 6GG

Dear Dr Butler

Study title: Platform Randomised trial of INterventions against COVID-19 In older peOPLE
REC reference: 20/SC/0158
Protocol number: PRINCIPLE
EudraCT number: 2020-001209-22
IRAS project ID: 281958

Thank you for your letter of 25th March 2020. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 24 March 2020

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Response to REC 25.03.20]		25 March 2020
IRAS Checklist XML [Checklist_25032020]		25 March 2020
Letters of invitation to participant [Test Message Invite]	1.0	24 March 2020

Participant information sheet (PIS) [PIS]	v1.0	24 March 2020
-------------------------------------------	------	---------------

Approved documents

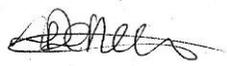
The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
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
IRAS Checklist XML [Checklist_25032020]		25 March 2020
Letter from sponsor [Sponsor Letter]		23 March 2020
Letters of invitation to participant [Test Message Invite]	1.0	24 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
Summary CV for Chief Investigator (CI) [Chris Butler CV 2020]		
Summary of product characteristics (SmPC) [SmPC_Plaquenil-Hydroxychloroquine]		

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

20/SC/0158	Please quote this number on all correspondence
-------------------	-------------------------------------------------------

Yours sincerely



Alison Doherty
Approvals Administrator

E-mail: berkshire.rec@hra.nhs.uk