

South Central - Berkshire Research Ethics Committee

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

22 April 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
Amendment number: SA3
Amendment date: 22 April 2020
IRAS project ID: 281958

Thank you for submitting the above amendment, which was received on 22 April 2020. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

Documents received

The documents to be reviewed are as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Annex 2: Notification of Amendment [AmendmentFormMHRAEudract_ReadyForSubmission (1)]	SA3	22 April 2020
Copies of advertisement materials for research participants [PRINCIPLE Patient recruitment Poster_v1.0 22.04.20]	1.0	22 April 2020
Letter from sponsor [SA3 Sponsor Approval 22.04.20]		22 April 2020
Other [PRINCIPLE TRIAL - text message info v1.2 20.04.2020_tc + clean]	1.2	20 April 2020
Other [PRINCIPLE TRIAL - text message info (111) v1.1 20.04.2020_tc + clean]	1.1	20 April 2020
Other [PRINCIPLE_Screening_v2.2_22Apr2020]	2.2	22 April 2020
Other [PRINCIPLE_Eligibility Information CRF_v2.3_21Apr2020]	2.3	21 April 2020
Other [PRINCIPLE_Call CRF_v2.2_21Apr2020]	2.2	21 April 2020
Participant consent form [PRINCIPLE Consent Form V1.2	1.2	21 April 2020

21.04.2020 tc + clean]		
Participant information sheet (PIS) [PRINCIPLE_Pictorial_Participant_Information_Sheet v1.0_20.04.2020]	1.0	20 April 2020
Participant information sheet (PIS) [PRINCIPLE PIS_ v2.1 21.04.2020_tc + clean]	2.1	21 April 2020
Participant information sheet (PIS) [PRINCIPLE Information for participants_v1.2_16Apr2020 tc + clean]	1.2	16 April 2020
Recruitment Arrangements [PRINCIPLE patient recruitment letter v1.0 22.04.2020]	1.0	22 April 2020
Research protocol or project proposal [Principle Protocol v2.1 21.04.2020 tc + clean]	2.1	21 April 2020
Sample diary card/patient card [PRINCIPLE_text message daily diaries_v2.0 31.03.20 tc + clean]	2.0	31 March 2020

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

20/SC/0158:

Please quote this number on all correspondence

Yours sincerely



Alison Doherty
Approvals Administrator

Email: berkshire.rec@hra.nhs.uk

Copy to: N/A N/A CTRG