

South Central - Berkshire Research Ethics Committee

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

04 May 2020

Christopher Butler
University of Oxford
Radcliffe Observatory Quarter, Woodstock Road
Oxford
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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: SA4
Amendment date: 30 April 2020
IRAS project ID: 281958

Thank you for submitting the above amendment, which was received on 01 May 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)]	SA4	30 April 2020
Copies of advertisement materials for research participants [PRINCIPLE Website Advert v1.0 01.05.20]	1.0	01 May 2020
Cover Letter [REC SA4 cover letter 01.05.20]		01 May 2020
GP/consultant information sheets or letters [PRINCIPLE GP Letter Scotland v1.0 01.05.20]	1.0	01 May 2020
Letter from sponsor [SA4 Sponsor Approval 01.05.20]		01 May 2020
Other [PRINCIPLE_Text Message Info (National 111)_v1.2_01.05.20_Clean]	1.2	01 May 2020
Other [PRINCIPLE_Text Message Daily Diaries 3.0 01.05.20_Clean]	3.0	01 May 2020
Other [PRINCIPLE TRIAL - Text Message Info v2.0 01.05.2020_Clean]	2.0	01 May 2020

Other [PRINCIPLE TRIAL - Text Message Info v2.0 01.05.2020_tracked]	2.0	01 May 2020
Other [PRINCIPLE_Email_London Ambulance 111_v1.0_01.05.20]	1.0	01 May 2020
Other [PRINCIPLE_Text Message Info (National 111)_v1.2_01.05.20_tracked]	1.2	01 May 2020
Sample diary card/patient card [PRINCIPLE_Text Message Daily Diaries 3.0 01.05.20_tracked]	3.0	01 May 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