

South Central - Berkshire Research Ethics Committee

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

20 May 2020

Christopher Butler
University of Oxford
Radcliffe Observatory Quarter, Woodstock Road
Oxford
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Dear Professor 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: SA5
Amendment date: 20 May 2020
IRAS project ID: 281958

Thank you for submitting the above amendment, which was received on 20 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 1: Clinical Trial Application Form [MhraProductsForm_ReadyForSubmission (1)]		20 May 2020
Annex 2: Notification of Amendment [AmendmentFormMHRAEudract_snapshot (1)]	SA5	20 May 2020
Copies of advertisement materials for research participants [PRINCIPLE Social Media v1.0 19.05.20]	1.0	19 May 2020
Copies of advertisement materials for research participants [PRINCIPLE Website Advert v1.1 12.05.20_tc + clean]	1.1	12 May 2020
Copies of advertisement materials for research participants [PRINCIPLE Patient Recruitment Poster_v1.2 19.05.20 tc + clean]	1.2	19 May 2020
Copies of advertisement materials for research participants [PRINCIPLE Care Home Staff Poster, v1.0 19.05.20]	1.0	19 May 2020
Cover Letter [REC SA5 cover letter]		20 May 2020
GP/consultant information sheets or letters [Medication Letter v1.0	1.0	19 May 2020

19.05.20]		
Letter from sponsor [SA5 Sponsor Approval]		20 May 2020
Letters of invitation to participant [PRINCIPLE Patient Recruitment Letter v2.0 19.05.2020_clean + tc]	2.0	19 May 2020
Letters of invitation to participant [Study Partner Letter v1.0 19.05.20]	1.0	19 May 2020
Letters of invitation to participant [Participant Introductory Letter v1.0 19.05.20]	1.0	19 May 2020
Non-validated questionnaire [PRINCIPLE_Baseline_v2.1_19May2020]	2.1	19 May 2020
Non-validated questionnaire [PRINCIPLE_Eligibility Information CRF_v3.1_19May2020]	3.1	19 May 2020
Non-validated questionnaire [PRINCIPLE_Screening_v4.1_19May2020]	4.1	19 May 2020
Organisation Information Document [OID_Trusts_Eligibility_PRINCIPLE]		
Other [PRINCIPLE NHS Testing Site Wording v1.0 19.05.2020]	1.0	19 May 2020
Other [PRINCIPLE TRIAL - Text Message Info v3.0 19.05.2020_tc + clean]	3.0	19 May 2020
Other [PRINCIPLE_IMP_Label form_azithromycin v1.3 17.05.20 250mg_tc + clean]	1.3	17 May 2020
Participant consent form [PRINCIPLE Consent Form V1.3 18.05.2020_tc + clean]	1.3	18 May 2020
Participant information sheet (PIS) [PRINCIPLE PIS_v3.0 19.05.2020_tc + clean]	3.0	19 May 2020
Participant information sheet (PIS) [PRINCIPLE_Pictorial PIS v2.0_19.05.2020_tc + clean]	2.0	19 May 2020
Participant information sheet (PIS) [PRINCIPLE Information for participants (SWAB)_v1.0_18.05.2020]	1.0	18 May 2020
Participant information sheet (PIS) [PRINCIPLE Information for participants_v1.3 18.05.2020 tc + clean]	1.3	18 May 2020
Research protocol or project proposal [Principle Protocol v3.0 19.05.2020_tc + clean]	3.0	19 May 2020
Sample diary card/patient card [Azithromycin Participant Card_v1.2_17.05.2020_tc + clean]	1.2	17 May 2020
Schedule of Events or SoECAT [SoECAT PRINCIPLE_Trust Eligibility_18MAY20]		
Summary of product characteristics (SmPC) [Azithromycin SmPC (Tevo)]		12 July 2019

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

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Copy to: N/A N/A CTRG