

South Central - Berkshire Research Ethics Committee

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

14 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: SA2
Amendment date: 07 April 2020
IRAS project ID: 281958

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Annex 2: Notification of Amendment [AmendmentFormMHRAEudract_ReadyForSubmission (1)]	SA2	07 April 2020
Cover Letter [REC SA2 cover letter 07.04.20]		07 April 2020
GP/consultant information sheets or letters [PRINCIPLE GP letter v1.1 07APR20_tc]	1.1	07 April 2020
Letter from sponsor [SA2 Sponsor Approval 09.04.20]		09 April 2020
Letters of invitation to participant [PRINCIPLE TRIAL - Participant new study invite v1.0 07.04.2020]	1.0	07 April 2020
Other [PRINCIPLE TRIAL - Participant Medication Receipt v1.0]	1.0	07 April 2020

07.04.2020]		
Other [PRINCIPLE TRIAL - Process evaluation invite v1.0 07.04.2020]	1.0	07 April 2020
Other [PRINCIPLE TRIAL - text message info version 1.1 07.04.2020]	1.1	07 April 2020
Other [PRINCIPLE_Baseline_v1.1_07Apr2020]	1.1	07 April 2020
Other [PRINCIPLE_Call CRF_v1.1_07Apr2020]	1.1	07 April 2020
Other [PRINCIPLE_Eligibility Information CRF_v1.4_08Apr2020]	1.4	08 April 2020
Other [PRINCIPLE_Screening_v1.4_08Apr2020]	1.4	08 April 2020
Other [MHRA Notice of Acceptance of Amendment]		09 April 2020
Participant consent form [PRINCIPLE Consent Form V1.1_07.4.2020_TT]	1.1	07 April 2020
Participant information sheet (PIS) [Substudy PIS]	1	08 April 2020
Research protocol or project proposal [Principle Protocol v2.0 07.04.2020 tracked]	2.0	07 April 2020
Sample diary card/patient card [PRINCIPLE_Daily Diary_v1.1_07Apr2020]	1.1	07 April 2020

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

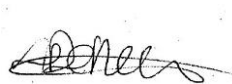
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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
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Yours sincerely
PP



Mr David Carpenter
Chair

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

Enclosures: List of names and professions of members who took part in the review

Copy to: N/A N/A CTRG

South Central - Berkshire Research Ethics Committee

Attendance at Sub-Committee of the REC meeting in correspondence.

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr David Carpenter	Retired Social Scientist	Yes	
Mike Proven		Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Alison Doherty	Approvals Administrator