

South Central - Berkshire Research Ethics Committee

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

**Please note: This is the
favourable opinion of the REC
only and does not allow the
amendment to be implemented
at NHS sites in England until
the outcome of the HRA
assessment has been
confirmed.**

22 May 2020

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

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

The above amendment was reviewed at the meeting of the Sub-Committee held 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>
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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 19.05.20]	1.0	19 May 2020
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 (Teva)]		12 July 2019

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

Thomas Fairman
HRA Approvals Manager

On behalf of

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: *CTRG*



Health Research Authority

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	
Dr Mike Proven		Yes	

Also in attendance:

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