

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 February 2021

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:	SA 12
Amendment date:	14 February 2021
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>
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Annex 2: Notification of Amendment [Annex 2]	n/a	19 February 2021
Completed Amendment Tool [Locked Amendment Tool_SA12]	n/a	19 February 2021
Cover Letter [REC SA12 cover letter]	n/a	19 February 2021
Investigator Brochure/SmPC [Colchicine SmPC]	n/a	05 August 2019
Letter from sponsor [SA12 Sponsor Approval]	n/a	19 February 2021
Letters of invitation to participant [PRINCIPLE Patient Recruitment Letter]	2.3	12 February 2021
Letters of invitation to participant [PRINCIPLE Patient Recruitment Letter_tracked]	2.3	12 February 2021
Other [Participant Introductory Letter]	1.2	12 February 2021
Other [Participant Introductory Letter_tracked]	1.2	12 February 2021
Other [PRINCIPLE NHS Testing Site Wording]	1.1	12 February 2021
Other [PRINCIPLE NHS Testing Site Wording_tracked]	1.1	12 February 2021
Other [Advert]	1.1	12 February 2021
Other [Advert_tracked]	1.1	12 February 2021
Other [PRINCIPLE GP Letter Scotland]	2.1	12 February 2021
Other [PRINCIPLE GP Letter Scotland_tracked]	2.1	12 February 2021
Other [PRINCIPLE Patient recruitment poster_pharmacy]	1.1	12 February 2021
Other [PRINCIPLE Patient recruitment poster_pharmacy_tracked]	1.1	12 February 2021
Other [PRINCIPLE Patient Recruitment Poster]	1.5	12 February 2021
Other [PRINCIPLE Patient Recruitment Poster_tracked]	1.5	12 February 2021
Other [PRINCIPLE PIS Appendices]	2.0	19 February 2021
Other [PRINCIPLE PIS Appendices_tracked]	2.0	19 February 2021
Other [Radio Advert]	1.1	12 February 2021
Other [Radio Advert_tracked]	1.1	12 February 2021
Other [PRINCIPLE Social Media]	1.2	12 February 2021
Other [PRINCIPLE Social Media_tracked]	1.2	12 February 2021
Other [PRINCIPLE Video Infographic Script]	1.2	12 February 2021
Other [PRINCIPLE Video Infographic Script_tracked]	1.2	12 February 2021
Other [PRINCIPLE Website Advert]	1.3	12 February 2021
Other [PRINCIPLE Website Advert_tracked]	1.3	12 February 2021
Other [PRINCIPLE_Translated video script]	1.1	12 February 2021
Other [PRINCIPLE_Translated video script_tracked]	1.1	12 February 2021
Other [Study Partner Letter]	1.2	12 February 2021
Other [Study Partner Letter_tracked]	1.2	12 February 2021
Other [Colchicine Participant Card]	1.0	19 February 2021
Other [IMP_Label form_Colchicine]	1.0	19 February 2021
Other [MhraProductsForm]	n/a	19 February 2021
Participant information sheet (PIS) [PIS]	3.5	14 February 2021
Participant information sheet (PIS) [PIS]	3.5	14 February 2021
Participant information sheet (PIS) [PRINCIPLE_Pictorial PIS]	2.4	12 February 2021
Participant information sheet (PIS) [PRINCIPLE_Pictorial PIS_tracked]	2.4	12 February 2021
Research protocol or project proposal [Protocol]	7.0	14 February 2021
Research protocol or project proposal [Protocol_tracked]	7.0	14 February 2021

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.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

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.

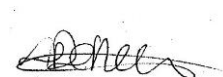
HRA Learning

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/>

IRAS Project ID - 281958:

Please quote this number on all correspondence

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	
Dr Mike Proven	University Research Governance Officer	Yes	

Also in attendance:

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