

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.

06 July 2020

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:	Substantial Amendment 6
Amendment date:	29th June 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.

Recommendation:

The Sub Committee recommended that a better description be used for purpura in the Doxycycline patient card.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Completed Amendment Tool [SA6 Amednment Tool]	1.0	02 July 2020
Cover Letter [SA6 Cover Letter]	1.0	02 July 2020
Letter from sponsor [SA6 Spomsor Approval]	1.0	02 July 2020
Letters of invitation to participant [Participant Introductory Letter (clean)]	1.1	02 July 2020
Letters of invitation to participant [Participant Introductory Letter (tracked)]	1.1	02 July 2020
Letters of invitation to participant [Patient Recruitment Letter]	2.1	02 July 2020
Letters of invitation to participant [Partient Recruitment Letter (tracked)]	2.1	02 July 2020
Letters of invitation to participant [Text Message Invite (clean)]	3.2	02 July 2020
Letters of invitation to participant [Text Message Invite (tracked)]	3.2	02 July 2020
Other [Doxycycline Participant Card]	1.0	02 July 2020
Other [Doxycycline IMP Label]	1.0	02 July 2020
Other [Hydroxychloroquine Medication Card (clean)]	1.1	02 July 2020
Other [Hydroxychloroquine Medication Card (tracked)]	1.1	02 July 2020
Other [Participant New Study Invite (clean)]	1.1	02 July 2020
Other [Participant New Study Invite (tracked)]	1.1	02 July 2020
Other [PIS Appendices (clean)]	1.2	02 July 2020
Other [PIS Appendices (tracked)]	1.2	02 July 2020
Other [Advert]	1.0	02 July 2020
Other [Radio Advert]	1.0	02 July 2020
Other [Social Media (clean)]	1.1	02 July 2020
Other [Social Media (tracked)]	1.1	02 July 2020
Other [Website Advert (clean)]	1.2	02 July 2020
Other [Website Advert (tracked)]	1.2	02 July 2020
Other [Patient Recruitment Poster (clean)]	1.3	02 July 2020
Other [Patient Recruitment Poster (tracked)]	1.3	02 July 2020
Participant information sheet (PIS) [PIS (clean)]	3.1	02 July 2020
Participant information sheet (PIS) [PIS (tracked)]	3.1	02 July 2020
Participant information sheet (PIS) [Pictorial PIS (clean)]	2.1	02 July 2020
Participant information sheet (PIS) [Pictorial PIS (tracked)]	2.1	02 July 2020
Research protocol or project proposal [Protocol (clean)]	4.0	02 July 2020
Research protocol or project proposal [Protocol (tracked)]	4.0	02 July 2020
Summary of product characteristics (SmPC) [Doxycycline SmPC]	0	02 July 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.

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.

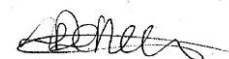
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

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/>

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	
Dr Mike Proven		Yes	

Also in attendance:

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