

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.**

12 November 2020

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

Dear Christopher 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: SA10
Amendment date: 04 November 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>
Completed Amendment Tool [SA10 Locked Amendment Tool]	N/A	04 November 2020
Cover Letter [REC SA10 cover letter]	N/A	09 November 2020
Other [Inhaled Corticosteroid Participant Card]	1.0	07 November 2020

Other [IMP_Label form_Inhaled corticosteroid]	1.0	07 November 2020
Other [Privacy Notice]	1.1	07 November 2020
Other [Privacy Notice (tracked)]	1.1	07 November 2020
Other [UPH Approval]	N/A	29 October 2020
Other [Information for participants]	1.1	09 November 2020
Other [Information for participants (tracked)]	1.1	09 November 2020
Other [Patient Recruitment Letter]	2.2	09 November 2020
Other [Patient Recruitment Letter (tracked)]	2.2	09 November 2020
Other [Video infographic script]	1.1	09 November 2020
Other [Video infographic script (tracked)]	1.1	09 November 2020
Other [Study Partner Letter]	1.1	09 November 2020
Other [Study Partner Letter (tracked)]	1.1	09 November 2020
Participant consent form [Consent Form]	2.1	07 November 2020
Participant consent form [Consent Form (tracked)]	2.1	07 November 2020
Participant information sheet (PIS) [PIS Appendices]	1.3	07 November 2020
Participant information sheet (PIS) [PIS Appendices (tracked)]	1.3	07 November 2020
Participant information sheet (PIS) [PIS]	3.3	07 November 2020
Participant information sheet (PIS) [PIS (tracked)]	3.3	07 November 2020
Participant information sheet (PIS) [Pictorial PIS]	2.3	09 November 2020
Participant information sheet (PIS) [Pictorial PIS (tracked)]	2.3	09 November 2020
Study Design [Protocol]	6.0	02 November 2020
Study Design [Protocol (tracked)]	6.0	02 November 2020
Summary of product characteristics (SmPC) [Pulmicort Turbohaler 400_SMPC]	N/A	14 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.

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.

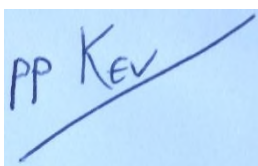
HRA Learning

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



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*

South Central - Berkshire Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 20 November 2020

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