

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.

28 April 2021

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

Dear Professor Butler

Study title: Platform Randomised trial of treatments in the Community for epidemic and Pandemic influenza
REC reference: 20/SC/0158
Protocol number: PRINCIPLE
EudraCT number: 2020-001209-22
Amendment number: SA 15
Amendment date: 26 April 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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Completed Amendment Tool [SA15 Locked Amendment Tool]	n/a	27 April 2021
Cover Letter [Cover Letter]	n/a	27 April 2021
Investigator Brochure/SmPC [Investigator's Brochure]	2.0	21 April 2021
Letter from sponsor [SA15 Sponsor Approval]	n/a	27 April 2021
Other [PIS Appendices]	2.2	16 March 2021
Other [PIS Appendices (tracked)]	2.2	16 March 2021
Other [Ivermectin Participant Card]	1.0	15 March 2021
Other [IMP_Label form_Ivermectin]	1.0	15 March 2021
Other [Wallet Emergency Card_Ivermectin]	1.0	15 March 2021
Research protocol or project proposal [Protocol]	8.1	12 April 2021
Research protocol or project proposal [Protocol (tracked)]	8.1	12 April 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
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Yours sincerely
PP



Mr David Carpenter
Chair

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

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