

South Central - Berkshire Research Ethics Committee

Bristol REC Centre
Whitefriars
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Lewins Mead
Bristol
BS1 2NT

Tel: 0207 104 8372

29 July 2021

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

Dear Prof Butler

Study title: Platform Randomised trial of treatments in the Community
for epidemic and Pandemic illnesses
REC reference: 20/SC/0158
Protocol number: PRINCIPLE
EudraCT number: 2020-001209-22
Amendment number: Substantial Amendment 16
Amendment date: 12 July 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>
Completed Amendment Tool [SA16 Locked Amendment Tool]	n/a	20 July 2021
Confirmation of Clinical Trial Authorisation from MHRA and relevant correspondence [MHRA Notice of acceptance of Amendment]		22 July 2021
Copies of advertisement materials for research participants [PRINCIPLE Patient Recruitment Poster_v1.6 12.07.2021_clean]	1.5	12 July 2021
Copies of advertisement materials for research participants [PRINCIPLE Patient Recruitment Poster_v1.6 12.07.2021_tracked]	1.5	12 July 2021
Copies of advertisement materials for research participants [PRINCIPLE Website Advert v1.4 12.07.21_clean]	1.4	12 July 2021
Copies of advertisement materials for research participants [PRINCIPLE Website Advert v1.4 12.07.21_tracked]	1.4	12 July 2021

Copies of advertisement materials for research participants [PRINCIPLE Advert v1.2 12.07.21_clean]	1.2	12 July 2021
Copies of advertisement materials for research participants [PRINCIPLE Advert v1.2 12.07.21_tracked]	1.2	12 July 2021
Copies of advertisement materials for research participants [PRINCIPLE Radio Advert v1.1 12.07.2021_clean]	1.1	12 July 2021
Copies of advertisement materials for research participants [PRINCIPLE Radio Advert v1.1 12.07.2021_tracked]	1.1	12 July 2021
Copies of materials calling attention of potential participants to the research [PRINCIPLE Social Media v1.3 12.07.2021_clean]	1.3	12 July 2021
Copies of materials calling attention of potential participants to the research [PRINCIPLE Social Media v1.3 12.07.2021_tracked]	1.3	12 July 2021
Cover Letter [REC SA16 Cover letter]	n/a	21 July 2021
Investigator Brochure/SmPC [Favipiravir IB]	13	06 July 2021
Investigator Brochure/SmPC [Favipiravir IB (tracked)]	13	06 July 2021
Investigator Brochure/SmPC [Ivermectin IB]	3	04 May 2021
Letter from sponsor [SA16 Sponsor Approval]	n/a	20 July 2021
Letters of invitation to participant [PRINCIPLE Patient Recruitment Letter v2.5 12.07.2021_clean]	2.5	12 July 2021
Letters of invitation to participant [PRINCIPLE Patient Recruitment Letter v2.5 12.07.2021_tracked]	2.5	12 July 2021
Letters of invitation to participant [PRINCIPLE_Study Partner Letter v1.4 12.07.21_clean]	1.4	12 July 2021
Letters of invitation to participant [PRINCIPLE_Study Partner Letter v1.4 12.07.21_tracked]	1.4	12 July 2021
Other [PRINCIPLE Text Message Info v4.2 12.07.2021_clean]	4.2	12 July 2021
Other [PRINCIPLE Text Message Info v4.2 12.07.2021_tracked]	4.2	12 July 2021
Other [PRINCIPLE_Video Infographic Script_1.4 12.07.2021_tracked]	1.4	12 July 2021
Other [PRINCIPLE_Participant Introductory Letter v1.3 12.07.2021_clean]	1.3	12 July 2021
Other [PRINCIPLE_Participant Introductory Letter v1.3 12.07.2021_tracked]	1.3	12 July 2021
Other [PRINCIPLE_Video Infographic Script_1.4 12.07.2021_clean]	1.4	12 July 2021
Other [PRINCIPLE Text Message IMP v1.0 14.07.2021]	1.0	14 July 2021
Participant information sheet (PIS) [PIS (tracked)]	4.1	12 July 2021
Participant information sheet (PIS) [PIS (clean)]	4.1	12 July 2021
Participant information sheet (PIS) [PRINCIPLE_Pictorial PIS v2.6 12.07.2021_clean]	2.6	12 July 2021
Participant information sheet (PIS) [PRINCIPLE_Pictorial PIS v2.6 12.07.2021_tracked]	2.6	12 July 2021
Participant information sheet (PIS) [PRINCIPLE PIS_v4.1 12.07.2021_clean]	4.1	12 July 2021
Participant information sheet (PIS) [PRINCIPLE PIS_v4.1 12.07.2021_tracked]	4.1	12 July 2021
Participant information sheet (PIS) [PRINCIPLE PIS Appendices_v2.3 12.07.2021_clean]	2.3	12 July 2021
Participant information sheet (PIS) [PRINCIPLE PIS Appendices_v2.3 12.07.2021_tracked]	2.3	12 July 2021
Research protocol or project proposal [Protocol (tracked)]	9.0	12 July 2021
Research protocol or project proposal [Protocol (clean)]	9.0	12 July 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. Philip Evans

**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*



Health Research Authority

South Central - Berkshire Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 30 July 2021

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr David Carpenter	Retired Social Scientist	Yes	Chair
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
Mr Philip Evans	Approvals Administrator