

South Central - Berkshire Research Ethics Committee

Bristol REC Centre
Temple Quay House
2 The Square
Temple Quay
Bristol
BS1 6PN

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.

21 November 2022

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

Dear Professor Butler

Study title:	Platform Adaptive trial of NOvel antiViRals for eArly treatMent of covid-19 In the Community
REC reference:	21/SC/0393
Protocol number:	PANORAMIC
EudraCT number:	2021-005748-31
Amendment number:	Substantial Amendment 6
Amendment date:	06 October 2022
IRAS project ID:	1004274

The above amendment was reviewed at the meeting of the Sub-Committee held on 21 November 2022 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>
Amendment Summary [AmendmentSummary]		17 November 2022
Annex 2: Notification of Amendment/Amendment tool [Locked Amendment Tool]	1.6	15 November 2022
Cover Letter [Cover Letter]	N/A	15 November 2022
EudraCT PDF [Medicines Information]		17 November 2022
Investigator Brochure/SmPC [SmPC Paxlovid]	N/A	16 August 2022
Investigator Brochure/SmPC [SmPC Molnupiravir]	N/A	11 July 2022
Miscellaneous [Privacy Notice Tracked]	3.0	15 November 2022
Miscellaneous [Privacy Notice Clean]	3.0	15 November 2022
Miscellaneous [IMP Returns Envelope Instructions Clean]	1.0	19 October 2022
Miscellaneous [GP Letter Tracked]	2.0	23 September 2022
Miscellaneous [GP Letter Clean]	2.0	23 September 2022
Miscellaneous [GP Letter Participant Follow-up Tracked]	2.0	15 November 2022
Miscellaneous [GP Letter Participant Follow-Up Clean]	2.0	15 November 2022
Miscellaneous [Confirmation of Consent Letter]	1.0	14 November 2022
Participant information and informed consent form [PIS Tracked]	6.0	15 November 2022
Participant information and informed consent form [PIS Clean]	6.0	15 November 2022
Participant information and informed consent form [Pictorial PIS Tracked]	3.0	15 November 2022
Participant information and informed consent form [Pictorial PIS Clean]	3.0	15 November 2022
Participant information and informed consent form [Paxlovid PIS Appendix Tracked]	3.0	15 November 2022
Participant information and informed consent form [Paxlovid PIS Appendix Clean]	3.0	15 November 2022
Participant information and informed consent form [Consent Form Tracked]	4.0	15 November 2022
Participant information and informed consent form [Consent Form Clean]	4.0	15 November 2022
Project Information - PDF [ProjectStudyInformation]		17 November 2022
Protocol [Protocol Tracked]	6.0	15 November 2022
Protocol [Protocol Clean]	6.0	15 November 2022
REC Application Form [Ethics]		17 November 2022

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

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 - 1004274:	Please quote this number on all correspondence
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Yours sincerely



pp
Ms Susan Tonks
Chair

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

Enclosures: List of names and professions of members who took part in the review

South Central - Berkshire Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 21 November 2022

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr David Carpenter	Retired Social Scientist	Yes	
Dr John Andrew Sutton	Medical Director	Yes	
Ms Susan Tonks	Clinical Research Project Regulatory & Manager	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Dayheem Sedighi	Approvals Administrator