

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.

11 April 2023

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 8
Amendment date:	22 March 2023
IRAS project ID:	1004274

The above amendment was reviewed at the meeting of the Sub-Committee held on 07 April 2023 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]		23 March 2023
Annex 2: Notification of Amendment/Amendment tool [PANORAMIC_SA08_LockedAmendmentTool]	1.6	22 March 2023
Cover Letter [PANORAMIC_RegulatoryCoverLetter]	N/A	23 March 2023
Participant information and informed consent form [PANORAMIC_PaxlovidPISAppendix_Trackedchanges]	4.0	23 March 2023
Participant information and informed consent form [PANORAMIC_PaxlovidPISAppendix]	4.0	23 March 2023
Project Information - PDF [ProjectStudyInformation]		23 March 2023
Protocol [PANORAMIC_Protocol_Trackedchanges]	7.0	23 March 2023
Protocol [PANORAMIC_Protocol]	7.0	23 March 2023
REC Application Form [Ethics]		23 March 2023

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

Copy to:

South Central - Berkshire Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 07 April 2023

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
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 William Lyse	Approvals Administrator
Mr Dayheem Sedighi	Approvals Administrator