

South Central - Berkshire Research Ethics Committee

Health Research Authority
2 Redman Place
Stratford
E20 1JQ

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.

26 March 2024

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 12
Amendment date:	02 February 2024
IRAS project ID:	1004274

The above amendment was reviewed at the meeting of the Sub-Committee held on 15 March 2024 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]		11 March 2024
Annex 2: Notification of Amendment/Amendment tool [Amendment Tool]	1.6	02 February 2024
Cover Letter [Regulatory Cover Letter SA12]	NA	11 March 2024
Investigator Brochure/SmPC [SmPC Paxlovid 16Jan2024]	NA	16 January 2024
Participant information and informed consent form [Paxlovid PIS Appendix]	5	26 February 2024
Participant information and informed consent form [Paxlovid PIS Appendix - Tracked]	4.1	12 February 2024
Participant information and informed consent form [Paxlovid Participant Card]	2	26 February 2024
Participant information and informed consent form [Paxlovid Participant Card - Tracked]	1.1	12 February 2024
Project Information - PDF [ProjectStudyInformation]		11 March 2024
Protocol [Protocol]	9	26 February 2024
Protocol [Protocol - Tracked]	8.1	07 February 2024
REC Application Form [Ethics]		11 March 2024

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/>

Yours sincerely

William Lyse

Approvals Administrator

On behalf of

**Mr Neil Thomas (Tom) O'Kane
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 15 March 2024

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Neil Thomas (Tom) O'Kane	Aviation Safety Consultant	Yes	(Chair)
Dr Deborah Scholey	Regulatory Affairs Consultant	Yes	

Also in attendance:

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