

South Central - Berkshire Research Ethics Committee

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

04 March 2022

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: SA02

Amendment date: 02 March 2022

IRAS project ID: 1004274

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:

Document	Version	Date
Amendment Summary [AmendmentSummary]		03 March 2022
Annex 2: Notification of Amendment [SA02 Locked Amendment Tool]	Template 1.6/06/Dec/2 021	02 March 2022
Cover Letter [PANORAMIC SA02 Cover Letter]	N/A	03 March 2022
EudraCT PDF [Medicines Information]		03 March 2022
Investigator Brochure/SmPC [Paxlovid Summary of Product Characteristics]	N/A	11 January 2022
Participant information and informed consent form [Participant Information Booklet Tracked]	2.0	02 March 2022
Participant information and informed consent form [Participant Information Booklet Clean]	2.0	02 March 2022
Participant information and informed consent form [Virology Participant Instructions Less Intensive Sampled Cohort]	1.0	02 March 2022
Participant information and informed consent form [Virology Participant Instructions Intensive Virology Sampled Cohort]	1.0	02 March 2022
Participant information and informed consent form [Virology Participant Instructions Dried Blood Spots]	1.0	02 March 2022
Participant information and informed consent form [Participant Wallet Emergency Card Paxlovid]	1.0	02 March 2022
Participant information and informed consent form [Pregnant Partner Participant Information Sheet Tracked]	2.0	02 March 2022

Participant information and informed consent form [Pregnant Partner Participant Information Sheet Clean]	2.0	02 March 2022
Participant information and informed consent form [Pregnant Partner Informed Consent Form Tracked]	2.0	02 March 2022
Participant information and informed consent form [Pregnant Partner Participant Informed Consent Form Clean]	2.0	02 March 2022
Participant information and informed consent form [Participant Pictorial Participant Information Sheet Tracked]	2.0	02 March 2022
Participant information and informed consent form [Participant Pictorial Participant Information Sheet Clean]	2.0	02 March 2022
Participant information and informed consent form [Participant Information Sheet Clean]	3.0	02 March 2022
Participant information and informed consent form [Participant Information Sheet Tracked]	3.0	02 March 2022
Participant information and informed consent form [Paxlovid PIS Appendicies]	1.0	02 March 2022
Participant information and informed consent form [Paxlovid Participant Card]	1.0	02 March 2022
Participant information and informed consent form [Molnupiravir PIS Appendicies Tracked]		02 March 2022
Participant information and informed consent form [Molnupiravir PIS Appendicies Clean]	2.0	02 March 2022
Participant information and informed consent form [Molnupiravir Participant Card Tracked]	2.0	02 March 2022
Participant information and informed consent form [Molnupiravir Participant Card Clean]	2.0	02 March 2022
Participant information and informed consent form [Consent Form Clean]	2.0	02 March 2022
Participant information and informed consent form [Consent Form Tracked]	2.0	02 March 2022
Project Information - PDF [ProjectStudyInformation]		03 March 2022
Protocol [Protocol Tracked]	2.0	02 March 2022
Protocol [Protocol Clean]	2.0	02 March 2022
REC Application Form [Ethics]		03 March 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

Yours sincerely



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

South Central - Berkshire Research Ethics Committee Attendance at Sub-Committee of the REC meeting on 11 March 2022

Committee Members:

Name	Profession	Present	Notes
Mr David Carpenter	Retired Social Scientist	Yes	
Mr Mike Proven		Yes	

Also in attendance:

Name	Position (or reason for attending)
Mr Frank Macdonald	Appovals Administrator