

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.

27 June 2022

Dear All,

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 5** Amendment date: 05 May 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] | | 13 June 2022 |

| Annex 2: Notification of Amendment/Amendment tool [Amendment Tool] | 1.6 | 05 May 2022 |
|---|-----|---------------|
| Cover Letter [Regulatory Cover Letter] | N/A | 10 May 2022 |
| Miscellaneous [Supporting Information] | N/A | 28 April 2022 |
| Miscellaneous [Privacy Notice Tracked] | 2.0 | 06 May 2022 |
| Miscellaneous [Privacy Notice Clean] | 2.0 | 06 May 2022 |
| Participant information and informed consent form [Participant Information Sheet Tracked] | 5.0 | 09 May 2022 |
| Participant information and informed consent form [Participant Information Sheet Clean] | 5.0 | 09 May 2022 |
| Participant information and informed consent form [Consent Form Tracked] | 3.0 | 09 May 2022 |
| Participant information and informed consent form [Consent Form Clean] | 3.0 | 09 May 2022 |
| Project Information - PDF [ProjectStudyInformation] | | 13 June 2022 |
| Protocol [Protocol Tracked] | 5.0 | 09 May 2022 |
| Protocol [Protocol Clean] | 5.0 | 09 May 2022 |
| REC Application Form [Ethics] | | 13 June 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: <u>https://www.hra.nhs.uk/planning-and-improving-research/learning/</u>

| IRAS Project ID - 1004274: Please quote this number on all correspondence |) |
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|---|--------------|

Yours sincerely

pp. Frank Macdonald Approvals Administrator

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

Copy to: