Health Research Authority

South Central - Berkshire Research Ethics Committee
Bristol REC Centre
Temple Quay House
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Temple Quay
Bristol
BS1 6PN

Telephone: 0207 104 8085

19 November 2021

Dr Christopher Butler
University of Oxford
Department of Primary Care and Health Sciences, Radcliffe Observatory Quarter
Oxford
OX2 6GG

Dear Dr 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**
IRAS project ID:	**1004274**

Thank you for your letter of 19 Novermber 2021, responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information was considered at the meeting of the Committee held on 16 November 2021. A list of the members who were present at the meeting is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as the first four project categories in IRAS project filter question 2. Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by or on behalf of the Research Ethics Committee (see here for more information on requesting a deferral: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/research-registration-research-project-identifiers/

If you have not already included registration details in your IRAS application form, you should notify the REC of the registration details as soon as possible.

For CTIMPs involving both UK and EU sites a record in the EU Clinical Trials Register (other than adult Phase 1 studies) will exist and will satisfy the requirement for registration.

For CTIMPs only taking place in the UK, sponsors must register the trial on an established international registry which is a Primary Registry listed in the WHO Registry Network or the ICMJE list of registries e.g. the ISRCTN registry or ClinicalTrials.gov.

You should notify *both* the REC and the MHRA of the registration details.

Further guidance on registration is available at:
https://www.hra.nhs.uk/planning-and-improving-research/research-planning/transparency-responsibilities/

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit:
https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

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 haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at:
https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/

Clinical trial authorisation must be obtained from the Medicines and Healthcare products Regulatory Agency (MHRA).

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators

- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Copies of materials calling attention of potential participants to the research [Promotional Material]	1	08 November 2021
Copies of materials calling attention of potential participants to the research [Legal Representative]	1	08 November 2021
Cover Letter [REC Cover Letter]	1	08 November 2021
GP/consultant information sheets or letters [Pregnant Partner GP Letter]	1	08 November 2021
GP/consultant information sheets or letters [GP Letter-Follow up]	1	08 November 2021
GP/consultant information sheets or letters [GP Letter]	1	08 November 2021
Letter from funder [Funder Letter]	1	08 November 2021
Letter from sponsor [Sponsor Letter]	1	08 November 2021
Letters of invitation to participant [Patient Recruitment Letter]	1	08 November 2021
Miscellaneous [HAF Approval]	1	08 November 2021
Miscellaneous [CRFs]	1	08 November 2021
Other [PANORAMIC_PregnancyTestInstructions_V1.0_16Nov2021]	1.0	16 November 2021
Participant information and informed consent form [Pregnant Partner ICF]	1	08 November 2021
Participant information and informed consent form [Pregnant Partner]	1	08 November 2021
Participant information and informed consent form [Pictorial PIS]	1	08 November 2021

Participant information and informed consent form [PIS – Clean and Tracked]	2.0	19 November 2021
Participant information and informed consent form [Trial Partner Letter]	1	08 November 2021
Participant information and informed consent form [End of Follow Up Letter]	1	08 November 2021
Participant information and informed consent form [Privacy Notice]	1	08 November 2021
Participant information and informed consent form [Information Booklet]	1	08 November 2021
Participant information and informed consent form [Wallet Emergency Card]	1	08 November 2021
Participant information and informed consent form [Molnupiravir Participant Card]	1	08 November 2021
Participant information and informed consent form [Consent]	1	08 November 2021
Proof of Insurance [Insurance Letter]	1	08 November 2021
Protocol [Protocol – Clean and Tracked]	1.2	18 November 2021
REC Application Form [Ethics]		10 November 2021
Suitability of the investigator/Investigator CV [CV]	1	08 November 2021

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

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

With the Committee's best wishes for the success of this project.

Yours sincerely

pp.
Mr David Carpenter
Chair

Email:berkshire.rec@hra.nhs.uk

Enclosed: List of names and professions of members who were present at the meeting and those who submitted written comments
After ethical review – guidance for sponsors and investigators - CTIMP Standard Conditions of Approval

Copy to: Dr Christopher Butler, University of Oxford
England: approvals@hra.nhs.uk

South Central - Berkshire Research Ethics Committee

Attendance at Committee meeting on 16 November 2021

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Rebecca Aylward	Retired Consultant Neurologist	Yes	
Mr David Carpenter	Retired Social Scientist	Yes	
Ms Nicola Greenberg	Clinical Pharmacist	Yes	
Mr Martin Hopkinson	Director of risk management services	Yes	
Mrs Liz Hunter	Retired Midwife and Clinical Governance Manager	Yes	
Mr Daniel Charles Mace	Retired Corporate Lawyer	Yes	
Mr Neil Thomas (Tom) O'Kane	Aviation Safety Consultant	No	
Dr Joanne Philpot	Consultant Paediatrician	No	
Dr Mike Proven	University Research Governance Officer	Yes	
Ms Ann Quinn	Social Worker	Yes	
Mrs Monika Rybacka-Brooke	Assistant Professor of Nursing	Yes	
Dr Deborah Scholey	Regulatory Affairs Consultant	Yes	
Dr John Andrew Sutton	Medical Director	Yes	
Ms Susan Tonks	Senior Research Support Associate	Yes	
Mrs Helen Turner	Clinical Study Manager	Yes	
Miss Hebe Weir	Operations (Aviation) and Student	No	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Kevin Ahmed	Approvals Manager
Nabeela Iqbal	Approvals Specialist
Dr Chris Kitchen	Approvals Manager
Mr Frank Macdonald	Appovals Administrator