

**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.**

10 March 2022

Christopher Butler  
University of Oxford  
Radcliffe Observatory Quarter, Woodstock Road  
Oxford  
OX2 6GG

Dear Dr Butler

<b>Study title:</b>	<b>Platform Randomised trial of treatments in the Community for epidemic and Pandemic influenza</b>
<b>REC reference:</b>	<b>20/SC/0158</b>
<b>Protocol number:</b>	<b>PRINCIPLE</b>
<b>EudraCT number:</b>	<b>2020-001209-22</b>
<b>Amendment number:</b>	<b>Substantial Amendment 21</b>
<b>Amendment date:</b>	<b>14 January 2022</b>
<b>IRAS project ID:</b>	<b>281958</b>

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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Annex 1: Clinical Trial Application Form [MHRA Products Form]	v6.2	07 March 2022
Completed Amendment Tool [Amendment Tool]	v1.6	06 December 2021
Covering letter on headed paper [REC Cover Letter]	v1.0	08 March 2022
Investigator Brochure/SmPC [Favipiravir Investigator Brochure]	v3.0	03 February 2022
Other [Privacy Notice (clean version)]	v2.0	03 February 2022
Other [IMP Return Letter]	v1.0	16 December 2021
Other [Favipiravir Participant Card (clean version)]	v2.0	24 January 2022
Other [Privacy Notice (tracked)]	v2.0	03 February 2022
Other [IMP Label Favipiravir (tracked)]	v2.0	03 February 2022
Other [Favipiravir Participant Card (tracked)]	v2.0	24 January 2022
Other [IMP Label Favipiravir (clean)]	v2.0	03 February 2022
Participant information sheet (PIS) [Patient Information Sheet (clean version)]	v8.0	17 January 2022
Participant information sheet (PIS) [PIS Appendices (clean version)]	v4.0	17 January 2022
Participant information sheet (PIS) [PIS Appendices (tracked)]	v4.0	17 January 2022
Participant information sheet (PIS) [Patient Information Sheet (tracked)]	v8.0	17 January 2022
Research protocol or project proposal [Protocol (clean version)]	v13.0	14 January 2022
Research protocol or project proposal [Protocol (tracked)]	v13.0	14 January 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**

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.

## **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/>

<b>IRAS Project ID - 281958:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely

pp. Frank Macdonald

**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: N/A N/A CTRG*

