

**East of England - Cambridgeshire and Hertfordshire Research Ethics Committee**

2 Redman Place  
London  
EC20 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.**

09 April 2024

Professor Christopher Butler  
Director, Primary Care Clinical Trials Unit, University of Oxford  
University of Oxford  
Nuffield Department of Primary Care Health Sciences  
Radcliffe Observatory Quarter, Woodstock Road  
Oxford  
OX2 6GG

Dear Professor Butler,

<b>Study title:</b>	<b>Perpetual Observational Study (POS) of Acute Respiratory Infections (ARI) in primary care settings (PC) across Europe.</b>
<b>REC reference:</b>	<b>23/EE/0050</b>
<b>Protocol number:</b>	<b>POS-ARI-PC AUDIT &amp; CORE</b>
<b>Amendment number:</b>	<b>Substantial Amendment 04 (SA04)</b>
<b>Amendment date:</b>	<b>25 March 2024</b>
<b>IRAS project ID:</b>	<b>324504</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>
Completed Amendment Tool [POS-ARI-PC_SA04_Amendment Tool]	N/A	25 March 2024
Copies of materials calling attention of potential participants to the research [ECRAID-Base_POS-ARI-PC_Screen Advertisement]	1	21 March 2024
Copies of materials calling attention of potential participants to the research [ECRAID-Base_POS-ARI-PC_Pharmacy Poster]	1	21 March 2024
Covering letter on headed paper [POS-ARI-PC_Substantial Amendment 04_REC Cover Letter]	N/A	27 March 2024
Other [POS_ARI_PC_Case_Report_Form_D0 Sampling_Tracked]	2	20 March 2024
Other [POS_ARI_PC_Case_Report_Form_D0 Sampling]	2	20 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**

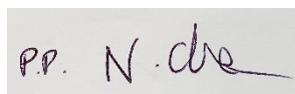
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### **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/>

<b>IRAS Project ID - 324504:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



**Dr Gerry Kamstra**  
Chair

E-mail: [cambsandherts.rec@hra.nhs.uk](mailto:cambsandherts.rec@hra.nhs.uk)

*Enclosures: List of names and professions of members who took part in the review*

*Copy to: Dr Nguyen Tran*

## East of England - Cambridgeshire and Hertfordshire Research Ethics Committee

### Attendance at Sub-Committee of the REC meeting on 05 April 2024

#### Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Oscar Hardy	Service Innovation Lead	Yes	
Dr Gerry Kamstra	Retired Solicitor	Yes	Meeting Chair

#### Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Natalie Wilson	Approvals Manager
Miss Nabeelah Chothia	Approvals Administrator