

South Central - Oxford C Research Ethics Committee

Health Research Authority (Bristol)
Ground Floor, Temple Quay House, 2 The Square
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.

26 August 2022

Professor Calum Semple
Institute of Child Health
University of Liverpool & Alder Hey Children's Hospital
Eaton Road
Liverpool
L12 2AP

Dear Professor Semple

Study title: Novel Coronavirus Observational Study
REC reference: 13/SC/0149
Amendment number: Substantial Amendment 13
Amendment date: 13 July 2022
IRAS project ID: 126600

The above amendment was reviewed at the meeting of the Sub-Committee held on 19 August 2022 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>
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Completed Amendment Tool [126600 Substantial Amendment 13]	13	13 July 2022
Participant information sheet (PIS) [PIS_Full_Adult_Data_and_Samples_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PIS_Full_Adult_Data_Only_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PIS_Full_Consultee_Data_and_Samples_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PIS_Full_Consultee_Data_Only_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PIS_Full_Parent_Guardian_Data_and_Samples_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PIS_Full_Parent_Guardian_Data_Only_v10.1]	Traced & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISA_Child_under12_Data_and_Samples_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISA_Child_under12_Data_Only_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISA_Child_under12_Extra_Convalescent_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISA_Consultee_In_Person_Data_and_Samples_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISA_Consultee_In_Person_Data_Only_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISA_Consultee_Tele_Data_and_Samples_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISA_Consultee_Tele_Data_Only_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISA_Young_12-16_Data_and_Samples_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISA_Young_12-16_Data_Only_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISA_Young_12-16_Extra Convalescent Sampling_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISC_Adult_Data_and_Samples_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISC_Adult_Data_Only_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISC_Adult_ExtraConvalescent_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISC_Adult_Samples_Genital_and_Data v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISC_Adult_Samples_Serial_Throat_and_Vesicles_and_Data v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISC_Adult_Serial_Serology_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISC_Adult_Tele_Data_and_Samples_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISC_Adult_Tele_Data_Only_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISC_At_Home_Data_and_Samples_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISC_At_Home_Data_Only_v10.1_22_08_2022]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISC_Bereaved_Relatives_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISC_Parent_Guardian_ExtraConvalescent_v10.1]	Tracked & Clean 10.1	22 August 2022

Participant information sheet (PIS) [PISC_Parent_Guardian_Tele_under_16y_Data_and_Samples_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISC_Parent_Guardian_Tele_under_16y_Data_Only_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISC_Parent_Guardian_under_16y_Data_and_Samples_v10.1]	Tracked & Clean 10.1	22 August 2022
Participant information sheet (PIS) [PISC_Parent_Guardian_under_16y_Data_Only_v10.1]	Tracked & Clean 10.1	22 August 2022
Research protocol or project proposal [ISARIC/WHO Clinical Characterisation Protocol UK]	10	27 July 2022
Research protocol or project proposal [ISARIC/WHO Clinical Characterisation Protocol UK (Tracked Changes)]	10	27 July 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 - 126600:	Please quote this number on all correspondence
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Yours sincerely



pp
Mrs Vivienne Laurie
Chair

E-mail: oxfordc.rec@hra.nhs.uk

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

Copy to: Ms Heather House

South Central - Oxford C Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 19 August 2022

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Vivienne Laurie	Barrister	Yes	
Dr Pamela Ross	GP Principal	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Dayheem Sedighi	Approvals Administrator