



Health Research Authority

South Central - Oxford C Research Ethics Committee

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27 May 2016 reissued

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

Dear Doctor Semple

Study title: Novel Coronavirus Observational Study
REC reference: 13/SC/0149
Amendment number: 5 (AM06)
Amendment date: 21 March 2016
IRAS project ID: 126600

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>
Covering letter on headed paper [CCP Cover Letter OxfordC REC 21MAR2016]		21 March 2016
Notice of Substantial Amendment (non-CTIMP) [IRAS AmendmentForm_ReadyForSubmission 21MAR2016]	5 (AM06)	21 March 2016
Other [Appendix A CCP Annual Activation Guidance v1 0 16MAR2016 track changes]	1.0	16 March 2016
Other [ISARIC CCP SPRINT-SARI UK Poster v1.2 13APR2016]	1.2	13 April 2016
Participant consent form [ISARIC SARI Internal Pilot CCP-Adult consent form V7.3 04MAR2016 clean]	7.3	04 March 2016
Participant consent form [ISARIC SARI Internal Pilot CCP-Child under 12 assent v7.2 12FEB2016 clean]	7.2	12 February 2016
Participant consent form [ISARIC SARI Internal Pilot CCP-	7.3	04 March 2016

Consultee consent v7.3 04MAR2016 clean]		
Participant consent form [ISARIC SARI Internal Pilot CCP-Parental Authority for C&YP v7.3 04MAR2016 clean]	7.3	04 March 2016
Participant consent form [ISARIC SARI Internal Pilot CCP-Young Person 12-16 Assent v 7.2 12FEB2016 clean]	7.2	12 February 2016
Participant consent form [ISARIC SARI CCP-Adult consent form V7.3 04MAR2016 track changes]	7.3	04 March 2016
Participant consent form [ISARIC SARI CCP-Child under 12 assent v7.2 13FEB2016 track changes]	7.2	13 February 2016
Participant consent form [ISARIC SARI CCP-Consultee consent v7.3 04MAR2016 track changes]	7.3	04 March 2016
Participant consent form [ISARIC SARI CCP-Parental Authority for C&YP v7.3 04MAR2016 track changes]	7.3	04 March 2016
Participant consent form [ISARIC VHF CCP-Young Person 12-16 Assent v 7.1 13FEB2016 track changes]	7.1	13 February 2016
Participant consent form [ISARIC VHF CCP-Adult consent form V7.2 04MAR2016 track changes]	7.2	04 March 2016
Participant consent form [ISARIC VHF CCP-Parental Authority for C&YP v7.2 04MAR2016 track changes]	7.2	04 March 2016
Participant consent form [ISARIC VHF CCP-Consultee consent v7.2 04MAR2016 track changes]	7.2	04 March 2016
Participant information sheet (PIS) [ISARIC SARI Internal Pilot CCP-Adult PIL V7.3 16MAR2016 clean]	7.3	16 March 2016
Participant information sheet (PIS) [ISARIC SARI Internal Pilot CCP-Child under 12 PIL v7.2 12FEB2016 clean]	7.2	12 February 2016
Participant information sheet (PIS) [ISARIC SARI Internal Pilot CCP-Consultee PIL v7.3 16MAR2016 clean]	7.3	16 March 2016
Participant information sheet (PIS) [ISARIC SARI Internal Pilot CCP-Parent-Guardian PIL v7.3 16MAR2016 track changes]	7.3	16 March 2016
Participant information sheet (PIS) [ISARIC SARI Internal Pilot CCP-Young Person 12-16 PIL v7.2 12FEB2016 clean]	7.2	12 February 2016
Participant information sheet (PIS) [ISARIC SARI CCP-Adult PIL V7.3 04MAR2016 track changes]	7.3	04 March 2016
Participant information sheet (PIS) [ISARIC SARI CCP-Consultee PIL v7.3 04MAR2016 track changes]	7.3	04 March 2016
Participant information sheet (PIS) [ISARIC SARI CCP-Parent-Guardian PIL v7.3 04MAR2016 track changes]	7.3	04 March 2016
Participant information sheet (PIS) [ISARIC SARI CCP-Young Person 12-16 PIL v7.2 13FEB2016 track changes]	7.2	13 February 2016
Participant information sheet (PIS) [ISARIC VHF CCP-Child under 12 PIL v7.1 13FEB2016 track changes]	7.1	13 February 2016
Participant information sheet (PIS) [ISARIC VHF CCP-Consultee PIL v7.2 04MAR2016 track changes]	7.2	04 March 2016
Participant information sheet (PIS) [ISARIC VHF CCP-Parent-Guardian PIL v7.2 04MAR2016 track changes]	7.2	04 March 2016
Participant information sheet (PIS) [ISARIC VHF CCP-Young Person 12-16 PIL v7.1 13FEB2016 track changes]	7.1	13 February 2016
Participant information sheet (PIS) [Cartoon PIL v7.2 14FEB2016 tracked Changes]	7.2	14 February 2016
Research protocol or project proposal [ISARIC CCP-SEI UK Protocol v7 3 21MAR2016 clean]	7.3	21 March 2016
Research protocol or project proposal [LIST OC CHANGES CCP Protocol v7.3 21MAR2016]	7.3	21 March 2016
Research protocol or project proposal [ISARIC CCP-SEI UK Protocol v7 3 21MAR2016 track changes]	7.3	21 March 2016
ISARIC SARI CCP-Young Person 12-16 assent v7.2 13FEB2016	7.2	13 February 2016
ISARIC VHF CCP-Adult PIL v7.2 04MAR2016	7.2	04 March 2016

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

13/SC/0149:	Please quote this number on all correspondence
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Yours sincerely



Pp Professor Nigel Wellman
Chair

E-mail: nrescommittee.southcentral-oxfordc@nhs.net

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

*Copy to: Dr Martin Gibson, Greater Manchester CLRN
Ms Heather House*

South Central - Oxford C Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 13 April 2016

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Leonard Brookes	Consultant to the Pharmaceutical Industry	Yes	
Professor Nigel Wellman (Chair)	Professor of Health and Human Sciences	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Sadie McKeown-Keegan	REC Assistant