



Health Research Authority

East of England - Cambridge East Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

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.

28 December 2018

Jenny King
Associate Director: Research
Picker Institute Europe
Buxton Court
3 West Way
Oxford
OX2 0JB

Dear Jenny King

Study title:	Community Mental Health Survey 2015
REC reference:	15/EE/0064
Amendment number:	4
Amendment date:	30 November 2018
IRAS project ID:	172654

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.

The subcommittee noted there is no revised protocol to set out the detail, only a summary of changes document. It was considered if the protocol should be updated and version-controlled for clarity.

The subcommittee agreed the amendment did not present any ethical issues and the protocol can be updated with the approval of this amendment as a non-substantial amendment or at the next update and submitted to the REC office for their files.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [20180823_MH19_Dissent Poster_V1.0_PROTECT.pdf]	1.0	23 August 2018
Letters of invitation to participant [20180907_MH19_First Mailing Letter_V1.0_PROTECT.doc]	1.0	07 September 2018
Letters of invitation to participant [20180907_MH19_First Reminder Letter_V1.0_PROTECT.doc]	1.0	07 September 2018
Letters of invitation to participant [20180907_MH19_Second Reminder Letter_V1.0_PROTECT.doc]	1.0	07 September 2018
Letters of invitation to participant [20181126_MH19_Multilanguage sheet_V1.0_PROTECT.pdf]	1.0	26 November 2018
Letters of invitation to participant [20181130_MH19_PILOT_Control_M1_First Mailing letter_V1.0_PROTECT.doc]	1.0	30 November 2018
Letters of invitation to participant [20181130_MH19_PILOT_Control_M2_First Reminder letter_V1.0_PROTECT.doc]	1.0	30 November 2018
Letters of invitation to participant [20181130_MH19_PILOT_Control_M3_Second Reminder letter_V1.0_PROTECT.doc]	1.0	30 November 2018
Letters of invitation to participant [20181130_MH19_PILOT_Intervention_M1_First mailing letter_V1.0_PROTECT.doc]	1.0	30 November 2018
Letters of invitation to participant [20181130_MH19_PILOT_Intervention_M2_First reminder email_V1.0_PROTECT.doc]	1.0	30 November 2018
Letters of invitation to participant [20181130_MH19_PILOT_Intervention_M3_First reminder letter_V1.0_PROTECT.doc]	1.0	30 November 2018
Letters of invitation to participant [20181130_MH19_PILOT_Intervention_M4_Second reminder email_V1.0_PROTECT.doc]	1.0	30 November 2018
Letters of invitation to participant [20181130_MH19_PILOT_Intervention_M5_Second reminder letter_V1.0_PROTECT.doc]	1.0	30 November 2018
Non-validated questionnaire [20181130_MH19_PILOT_Shorter questionnaire_V1.0_PROTECT.pdf]	1.0	30 November 2018
Non-validated questionnaire [20181130_MH19_Questionnaire_V1.0_PROTECT.pdf]	1.0	30 November 2018
Notice of Substantial Amendment (non-CTIMP) [CMH19_Notice of amendment_V1.0_PROTECT.pdf]	4	30 November 2018
Other [18CAG0183 Fully Supported Outcome.pdf]		16 November 2018
Other [20181130_MH19_Summary of changes_V1.0_PROTECT.docx]	1.0	30 November 2018
Other [MH19_IRAS notification of amendment_V1.0_AW_PROTECT.docx]	1.0	



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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.

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 Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

15/EE/0064: Please quote this number on all correspondence
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Yours sincerely

Dr Alan Lamont
Chair

E-mail: NRESCcommittee.EastofEngland-CambridgeEast@nhs.net

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

*Copy to: Tamatha Webster , Care Quality Commission
(CQC)Confidentiality Advise Team*



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Attendance at Sub-Committee of the REC meeting on 18 December 2018

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mrs Victoria Hollamby	Assistant Research Governance Advisor	Yes	
Dr Alan Lamont	Retired Consultant Oncologist	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Adam Garretty	REC Assistant