



# 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.**

21 December 2017

Tamatha Webster  
Care Quality Commission (CQC)  
151 Buckingham Palace Road  
London  
SW1W 9SZ

Dear Webster

<b>Study title:</b>	<b>Community Mental Health Survey 2015</b>
<b>REC reference:</b>	<b>15/EE/0064</b>
<b>Amendment number:</b>	<b>3</b>
<b>Amendment date:</b>	<b>05 December 2017</b>
<b>IRAS project ID:</b>	<b>172654</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.

The subcommittee agreed the change in the handling of the still-merged PID and data is reasonable in view of the CAG approval with various terms and conditions.

The subcommittee agreed the study is not substantially changing the nature of the research i.e. the aims, scope and methodology are basically the same, and the changes are to the details within the methodology and can continue to go through as amendments rather than resubmission. It was commented this amendment process can continue unless there is too much gradual incremental change introduced, or there has been a major advance in the field in the meantime.

The committee agreed the new documents are all acceptable but discussed the issue of the number of reminders could be considered high. It was noted in the field of mental health the response rates tend to be low for numerous reasons, including a high rate of chaos in their lives. Response rates are falling year on year for this study. It was agreed three letters do not present an

ethical issue as the applicant does confirm that anyone telling them they don't want any further contact will not be sent reminders.

The sub-committee stated the REC name should be added to the information sheets but this can be done without further submission to the REC and does not affect the favourable opinion.

The sub-committee agreed the amendment as submitted does not present any ethical issues.

## 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 [20171205_MH18_CQC flyer_V1.0_PROTECT.pdf]	1.0	05 December 2017
Copies of advertisement materials for research participants [20171205_MH18_Dissent Poster_V1.0_PROTECT.pdf]	1.0	05 December 2017
Copies of advertisement materials for research participants [20171205_MH18_Pilot_Dissent Poster_V1.0_PROTECT.pdf]	1.0	05 December 2017
Covering letter on headed paper [20171205_MH18_Ethics Submission_Covering_Letter_V1.0_PROTECT]		05 December 2017
Letters of invitation to participant [20171205_MH18_First Covering Letter_V1.0_PROTECT.pdf]	1.0	05 December 2017
Letters of invitation to participant [20171205_MH18_Second Covering Letter_V1.0_PROTECT.pdf]	1.0	05 December 2017
Letters of invitation to participant [20171205_MH18_Third Covering Letter_V1.0_PROTECT.pdf]	1.0	05 December 2017
Non-validated questionnaire [20171205_MH18_Pilot Shorter Questionnaire_V1.0_PROTECT.pdf]	1.0	05 December 2017
Non-validated questionnaire [P3154_MH18_Main Questionnaire_V11_TG_JLM_20171205_protect.pdf]	1.0	05 December 2017
Notice of Substantial Amendment (non-CTIMP) [20171205_MH18_2015 IRAS application_V1.0_PROTECT.pdf]	3	05 December 2017
Other [16CAG0041 amendment final approval letter.pdf]		01 August 2016
Other [7.CAG.0185 Conditional Outcome.pdf]		23 November 2017
Other [20171205_MH18_CV Chief_investigator_V1.0_PROTECT.docx]	1.0	05 December 2017
Other [20171205_MH18_Multilanguage_sheet_V1.0_PROTECT.]	1.0	05 December 2017
Other [20171205_MH18_Questionnaire_V1.0_PROTECT.pdf]	1.0	05 December 2017
Other [20171205_MH18_Summary of changes_V1.0_PROTECT.docx]	1.0	05 December 2017
Other [REC_Form_04022015 - Wet signed by new Chief Investigation Officer 201712....pdf]		06 December 2017

## 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/>

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



**Dr Alan Lamont  
Chair**

E-mail: [NRESCCommittee.EastofEngland-CambridgeEast@nhs.net](mailto:NRESCCommittee.EastofEngland-CambridgeEast@nhs.net)

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

*Copy to: Ms Jenny King, Picker Institute Europe Confidentiality Advise Team*



# Health Research Authority

East of England - Cambridge East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 19 December 2017

**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