Health Research Authority

London - Brent Research Ethics Committee
80 London Road
Skipton House
London
SE1 6LH

Telephone: 02071048129

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

17 July 2017

Prof Alicia O'Cathain
Professor of Health Services Research / Director of MCRU
University of Sheffield
ScHARR
University of Sheffield
Sheffield
S1 4DA

Dear Prof O'Cathain

Study title:	**Drivers of Demand for Emergency and Urgent CarE services (DEUCE): understanding patients' and public perspectives**
REC reference:	**17/LO/1228**
IRAS project ID:	**217875**

The Proportionate Review Sub-committee of the London - Brent Research Ethics Committee reviewed the above application in correspondence.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact hra.studyregistration@nhs.net outlining the reasons for your request. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be

possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [UoS_Employers Liability_Certificate]		
Interview schedules or topic guides for participants [DEUCE Interview topic guide va 070617]	1	07 June 2017
IRAS Application Form [IRAS_Form_29062017]		29 June 2017
Letter from funder [15_136_12 O'Cathain Final funding letter]	n/a	08 December 2016
Letters of invitation to participant [DEUCE Interview Confirmation Letter v1 180517]	1	18 May 2017
Letters of invitation to participant [DEUCE Focus Group interview confirmation letter v1 180517]	1	18 May 2017
Other [DEUCE consent to contact script v1 150517]	1	15 May 2017
Other [UoS_Public Liability]		15 November 2016
Other [UoS_Professional Indemnity]		26 September 2016
Participant consent form [DEUCE Interview Consent Form v1 070617]	1	07 June 2017
Participant consent form [DEUCE Focus Group Consent Form v1 070617]	1	07 June 2017
Participant information sheet (PIS) [DEUCE Interview Participant Information Sheet v1 200417]	1	20 April 2017
Participant information sheet (PIS) [DEUCE Focus Group Participant Information Sheet v1 200417]	1	20 April 2017
Referee's report or other scientific critique report [reviewers		

comments_DEUCE]		
Research protocol or project proposal [217875 publicproposal_v1_260117]	1	26 January 2017
Summary CV for Chief Investigator (CI) [AOC short cv 2017 deuce]		14 June 2017

Membership of the Proportionate Review Sub-Committee

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

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.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

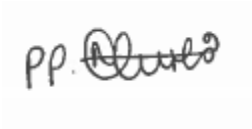
HRA Training

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

With the Committee's best wishes for the success of this project.

17/LO/1228 **Please quote this number on all correspondence**

Yours sincerely



Dr Manish Saxena
Chair

Email: nrescommittee.london-brent@nhs.net

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

"After ethical review – guidance for researchers" [SL-AR2]

Copy to: *Dr Emma Knowles, University of Sheffield*
Dr Erica Wallis, Sheffield Teaching Hospital NHS Foundation Trust

London - Brent Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting in correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Daniel Bradford	Pharmacologist	Yes	
Mrs Sunder Chita	Manager	Yes	
Dr Manish Saxena (Chair)	Clinical Lecturer	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Nicole Curtis	REC Manager

Health Research Authority

London - Brent Research Ethics Committee
80 London Road
Skipton House
London
SE1 6LH

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 June 2018

Dr Emma Knowles
Project Manager
University of Sheffield
School of Health and Related Research (ScHARR)
University of Sheffield
Regent Street, Sheffield
S1 4DA

Dear Dr Knowles

Study title:	**Drivers of Demand for Emergency and Urgent CarE services (DEUCE): understanding patients' and public perspectives**
REC reference:	**17/LO/1228**
Amendment number:	**1**
Amendment date:	**31 May 2018**
IRAS project ID:	**217875**

This substantial amendment sought approval for:

- Change to the recruitment process of focus group participants to recruit 8 individuals from each of the three sub groups
- Offering a telephone interview as an alternative to a face to face interview
- Extension of the age range inclusion criteria
  a. Parents with young children – to extend the age of children from 0-5 years to 0-10 years.
  b. Young adults – to extend the age range from 18-25 years to 18-30 years.

The above amendment was reviewed at the meeting of the Sub-Committee held on 15 June 2018.

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:

Document	*Version*	*Date*
Interview schedules or topic guides for participants [DEUCE Focus group topic guide v1 090518]	1	09 May 2018
Notice of Substantial Amendment (non-CTIMP) [AmendmentForm_217875_310518]	1	31 May 2018
Participant information sheet (PIS) [DEUCE Focus Group Participant Information Sheet v2 310518]	2	31 May 2018

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/

17/LO/1228:	**Please quote this number on all correspondence**

Yours sincerely

pp
Dr Manish Saxena
Chair

E-mail: nrescommittee.london-brent@nhs.net

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

Copy to: *Dr Erica Wallis, Sheffield Teaching Hospital NHS Foundation Trust*
Prof Alicia O'Cathain, University of Sheffield

London - Brent Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 15 June 2018

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Manish Saxena (Chair)	Clinical Lecturer	Yes	
Miss Zainab Yate	Bioethics Researcher	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Jake Chambers	REC Assistant