NRES Committee South Central - Berkshire
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18 November 2013

Dr Josip Car
Director, Global eHealth Unit
Imperial College London
Department of Primary Care and Public Health
Reynolds Building, St Dunstan's Road
LONDON
W6 8RP

Dear Dr Car,

Study title:	**How and why do people with long term conditions choose to use a smartphone or tablet app for their condition? A qualitative interview study.**
REC reference:	**13/SC/0603**
IRAS project ID:	**135097**

The Proportionate Review Sub-committee of the NRES Committee South Central - Berkshire reviewed the above application on 13 November 2013.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Ms Rae Granville, nrescommittee.southcentral-berkshire@nhs.net.

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.

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" below).

Conditions of the favourable opinion

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

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

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System 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 approvals 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 within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

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 contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made 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.

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).

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Advertisement	1.7	01 October 2013
Evidence of insurance or indemnity		29 July 2013
GP/Consultant Information Sheets	1.7	01 October 2013
Interview Schedules/Topic Guides	1.7	01 October 2013
Letter from Sponsor		31 October 2013
Other: CV - Dr J Car		
Other: CV - Dr Huckvale		
Other: Letter explaining CI Status		06 November 2013
Participant Consent Form	1.7	01 October 2013
Participant Information Sheet	1.7	01 October 2013
Protocol	1.7	01 October 2013
Questionnaire: ACQ		
Questionnaire: AQLQ		
Questionnaire: DQoL		
Questionnaire: BCI		
Questionnaire: STOFHLA		
Questionnaire: Online Screening Questionnaire Schedule	1.7	01 October 2013
REC application		06 November 2013

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

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.
information is available at National Research Ethics Service website > After Review

13/SC/0603	**Please quote this number on all correspondence**

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/

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

Yours sincerely,

Mr David Carpenter
Chair

Email: nrescommittee.southcentral-berkshire@nhs.net

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

After ethical review – guidance for researchers

Copy to: *Ms Becky Ward*
Ms Sylvia Westrup, West London Primary Care Research

NRES Committee South Central - Berkshire

Attendance at PRS Sub-Committee of the REC meeting on 13 November 2013

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr David Carpenter	Social Scientist	Yes	
Dr Mike Proven	Co-ordinator for QA in Research	Yes	
Ms Susan Tonks	Senior Research Support Associate	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Rae Granville	REC Manager