

London - Bromley Research Ethics Committee

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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

06 October 2017

Professor Stephen Leslie
Consultant Cardiologist
NHS Highland
Cardiac Unit
Raigmore Hospital
Inverness
IV2 3UJ

Dear Professor Leslie

Study title: A cross sectional survey of people with cardiac conditions; determining barriers and facilitators to achieving recommended levels of physical activity
REC reference: 17/LO/1389
IRAS project ID: 231385

Thank you for your letter of 06/10/2017, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

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 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.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

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” above).

Approved documents

The documents reviewed and approved by the Committee are:

| <i>Document</i> | <i>Version</i> | <i>Date</i> |
|---|----------------|-------------------|
| Covering letter on headed paper [cover letter] | 1 | 26 July 2017 |
| Covering letter on headed paper [cover letter] | 1 | 28 September 2017 |
| Interview schedules or topic guides for participants | 1 | 13 September 2017 |
| IRAS Application Form [IRAS_Form_06102017] | | 06 October 2017 |
| Letters of invitation to participant [part invite] | 1 | 26 July 2017 |
| Non-validated questionnaire [questionnaire] | 1 | 26 July 2017 |
| Other [Email re delay to response to PO] | | 08 September 2017 |
| Participant consent form [consent] | 2 | 13 September 2017 |
| Participant information sheet (PIS) [PIS] | 2 | 13 September 2017 |
| Participant information sheet (PIS) [PIS focus group] | 1 | |
| Research protocol or project proposal [protocol] | 2 | 28 September 2017 |
| Summary CV for Chief Investigator (CI) [CI CV] | na | 26 July 2017 |
| Summary CV for student [student CV] | na | 26 July 2017 |

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.

Feedback

You are invited to give your view of the service that you have received from the Research Ethics Service 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>

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

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Please quote this number on all correspondence

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

Yours sincerely



Ms Heather Salzer
Chair

Email: nrescommittee.london-bromley@nhs.net

Enclosures: “After ethical review – guidance for researchers”

Copy to: Mrs Frances Hines