NHS
Health Research Authority
National Research Ethics Service

NRES Committee West Midlands - Staffordshire
HRA NRES Centre Manchester
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[redacted]

28 November 2012

Professor Helen Spiby
Professor of Midwifery, Faculty of Medicine & Health Sciences
University of Nottingham
School of Nursing, Midwifery and Physiotherapy,
A Floor, Queen's Medical Centre
Nottingham
NG7 2RD

Dear Professor Spiby,

Study title:	**Multi-site implementation of a promising innovation in low income communities: support for childbearing women**
REC reference:	**12/WM/0342**
Protocol number:	**12099**
REC Identifier:	**97509**

Thank you for your letter of 13 November 2012, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

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 Rinat Jibli, nrescommittee.westmidlands-staffordshire@nhs.net.

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, subject to the conditions specified below.

Ethical review of research sites

NHS 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

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 final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Covering Letter		25 September 2012
REC application	3.4	25 September 2012
Protocol	1.0	21 September 2012
Evidence of Insurance or Indemnity - Henderson Corporate		25 July 2012
Interview Schedules/Topic Guides - Heads of Midwifery Interview Schedule Telephone Interviews	1.0	21 September 2012
Interview Schedules/Topic Guides - Midwives' Focus Groups Topic Guide	1.0	21 September 2012
Interview Schedules/Topic Guides - Midwives' Focus Groups Topic	1.0	21 September 2012
Investigator CV - Helen Spiby		25 September 2012
Letter from Sponsor - University of Nottingham		25 September 2012
Letter of Invitation to participant - Email to Midwives	1.0	21 September 2012
Letter of Invitation to participant – Women's' questionnaire	1.2	23 October 2012
Letter of Invitation to participant - Doulas' Questionnaire	1.2	23 October 2012

Other: Postcard Thanks/Reminder Women's Questionnaires	1.0	21 September 2012
Participant Consent Form: Telephone Interviews - Heads of Midwifery and Volunteer Doulas	1.2	23 October 2012
Participant Consent Form: Focus Groups - Midwives and Volunteer Doulas	1.2	23 October 2012
Participant Consent Form: Women's Focus Groups	1.2	23 October 2012
Participant Consent Form: Women's Telephone Interviews	1.2	23 October 2012
Participant Information Sheet: Women's Questionnaires	1.0	21 September 2012
Participant Information Sheet: Doulas Questionnaires	1.0	21 September 2012
Participant Information Sheet: Women's Focus Groups	1.2	23 October 2012
Participant Information Sheet: Women's Telephone Interview	1.2	23 October 2012
Participant Information Sheet: Doula Service Staff Focus Groups and Telephone Interview	1.2	23 October 2012
Participant Information Sheet: Head of Midwifery Telephone Interviews	1.2	23 October 2012
Participant Information Sheet: Midwives' Focus Group	1.2	23 October 2012
Response to Request for Further Information		13 November 2012

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.

Further information is available at National Research Ethics Service website > After Review

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

Yours sincerely

Signed on behalf of:
Dr Kathryn Kinmond
Chair

Email:nrescommittee.westmidlands-staffordshire@nhs.net

Enclosures: "After ethical review – guidance for Researchers

Copy to: Dr Paul Cartledge – The University of Nottingham

Mr James Illingworth - R&D Manager, Research & Development Department, Hull & East Yorkshire Hospitals NHS Trust