



05 March 2015

Dr Sarah Earle



Dear Dr Earle

Study title: Pre-conception care for women with type 1 or type 2 diabetes: What are the facilitators and barriers to uptake?
REC reference: 15/SC/0026
IRAS project ID: 156840

Thank you for your letter of 26 February 2015, 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 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 the REC Manager, Rae Granville, nrescommittee.southcentral-berkshire@nhs.net. 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, subject to the conditions specified 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. 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 NRES. 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

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).

Approved documents

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper [Cover letter NREC]		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		05 January 2015
GP/consultant information sheets or letters [Letter to Patient GP]	1.0	22 December 2014
GP/consultant information sheets or letters [Letter to GP (clean)]	2.0	13 February 2015
GP/consultant information sheets or letters [Letter to GP tracked]	2.0	13 February 2015
Interview schedules or topic guides for participants	1.0	19 December 2014
IRAS Checklist XML [Checklist_23122014]		23 December 2014
IRAS Checklist XML [Checklist_27022015]		27 February 2015
Letter from funder	1.0	
Letters of invitation to participant [Letter from GP to patient - clean]	2.0	13 February 2015
Letters of invitation to participant [Letter from doctor to patient - tracked]	2.0	13 February 2015
Letters of invitation to participant [Letter to stakeholders clean]	2.0	13 February 2015
Letters of invitation to participant [Letter to stakeholders - tracked]	2.0	13 February 2015
Other [Employers' Liability]		
Other [Employers' Liability]	2.0	01 January 2015
Other [New Cover Letter]	2.0	13 February 2015
Other [Protocol v2.0 TRACKED]	2.0	04 February 2015
Participant consent form [Consent Form Phase II v2.0 CLEAN]	2.0	04 February 2015
Participant consent form [Consent Form Phase II TRACKED CHANGES]	2.0	04 February 2015
Participant consent form [Consent Form Phase III v2.0]	2.0	04 February 2015
Participant consent form [Consent Form Phase III v2.0 TRACKED]	2.0	04 February 2015
Participant consent form [Consent Form Phase IV v2.0 TRACKED CHANGES]	2.0	04 February 2015
Participant consent form [Consent Form Phase IV CLEAN VERSION]	2.0	04 February 2015
Participant information sheet (PIS) [PIS Phase 2 v2.0 CLEAN]	2.0	04 February 2015
Participant information sheet (PIS) [PIS Phase II v2.0 TRACKED]	2.0	04 February 2015
Participant information sheet (PIS) [PIS Phase III v2.0 CLEAN]	2.0	04 February 2015
Participant information sheet (PIS) [PIS Phase III v2.0 TRACKED]	2.0	04 February 2015
Participant information sheet (PIS) [PIS Phase IV v2.0 TRACKED]	2.0	04 February 2015
Participant information sheet (PIS) [PIS Phase IV v2.0 CLEAN]	2.0	04 February 2015
REC Application Form [REC_Form_23122014]		23 December 2014

Referee's report or other scientific critique report [NIHR Peer Review]		
Research protocol or project proposal	2.0	04 February 2015
Summary CV for Chief Investigator (CI)	1.0	19 December 2014

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/>

15/SC/0026

Please quote this number on all correspondence
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With the Committee's best wishes for the success of this project.

Yours sincerely



pp
Mr David Carpenter
Chair

Email: [Redacted]

Enclosures: "After ethical review – guidance for researchers" [\[SL-AR2\]](#)

Copy to: **Mr Graham Mitchell, The Open University**
Ms Liz Adey, Heart of England NHS Foundation Trust