NRES Committee London - Harrow
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20 March 2013

Dr Valerie Delpech
Consultant Epidemiologist
Health Protection Agency
61 Colindale Avenue
NW9 5EQ

Dear Dr Delpech

Study title:	**Development and Implementation of Positive Voices: the National Survey of People Living with HIV**
REC reference:	**13/LO/0279**
Protocol number:	**108401**
IRAS project ID:	**108483**

The Research Ethics Committee reviewed the above application at the meeting held on 12 March 2013. Thank you for attending to discuss the application.

1. The Committee sought clarification of what stage 3 of the study would involve and whether it was also subject to the Committee's review at this time.

You confirmed that Phase 3 will be the national roll out of the survey alongside the on-going surveillance work that is already undertaken. The main focus of the ethics application is Phases 1 and 2.

2. The Committee queried whether the first discussion at the Focus Group would be around the confidentiality of the discussions.

You confirmed that participants would be reminded of the confidential nature of the focus group discussions at the beginning of the sessions.

The Committee stated that this should be re-iterated in the Focus Group PIS.

3. The Committee queried whether the inclusion of prize-draw incentives would compromise the confidentiality of participants.

You confirmed that they have trialled the use of prize-draws previously and it was designed so

that the prize-draw was an entirely separate web-page from the survey, so that the responses cannot be linked to a particular individual.

4. The Committee stated that someone would still then have access to a list of patients' names, but this would be for the researchers to consider.

You confirmed that participants will have to be specifically invited to complete this survey by their clinic. You also confirmed that the likelihood of being able to offer prize-draw incentives for survey completion in the future is questionable.

5. The Committee queried whether Phase 3 of the research will be subject to an ethics application.

You confirmed that, if after Phase 2 of the survey development, the survey is such that it would be used for public health action, the survey could be rolled out nationally without ethical approval. If Phase 2 has shown that changes need to be made to the questions in the survey, the amended survey would be submitted to an ethics committee.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Investigator CV		13 December 2012
Investigator CV		12 December 2013
Letter from Sponsor	1.0	06 February 2013
Other: Focus Group Discussion Topic Guide		
Participant Consent Form: Consent form Focus Group and Cognitive Interview	1.0	01 February 2013
Participant Consent Form: Consent Form National Survey	1.0	01 February 2013
Participant Information Sheet: Focus Group Discussion	1.0	01 December 2011
Participant Information Sheet: Cognitive Interview	1.0	01 December 2011
Participant Information Sheet: National Survey	1.0	01 December 2011
Protocol	4.0	01 February 2013
REC application	1.0	01 February 2013

Ethical Opinion

The members of the Committee present 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.

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 Libby Watson, nrescommittee.london-harrow@nhs.net.

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.

1. The Committee's approval applies to Phase 1 and Phase 2 of the research. All participant documentation needs to be reviewed and approved by the Committee, therefore the questionnaire/survey needs to be provided for review once it has been developed and after subsequent amendments. Advice should be sought about whether ethical approval is required before implementing Phase 3.

2. The Committee requests that the statement is added to the Focus Group Discussion PIS section
'Will my taking part in the study be kept confidential?': "All discussions during the Focus Group will be confidential to the participants involved in the discussion. You will be reminded of the confidential nature of the discussions at the beginning of the Focus Group session."

3. The Committee requests that a section is added to the PISs titled 'Who is organising and funding the research?' stating that: "This project is being organised by the Health Protection Agency and is funded by a grant from the NIHR Centre for Public Health Research".

4. The Committee asks that the statement in the PISs is amended to: "This study has been approved by the London – Harrow Research Ethics Committee".

5. The Committee requests that a statement is added to the section 'Do I have to take part?' in the PISs to state that: "If you withdraw, any information you have provided up to the point of withdrawal will still be used for the purposes of the study."

6. The Committee requests that the following standard statement is added as an item to the Consent Form:
"I understand that relevant sections of my [medical] notes and data collected during the study, may be looked at by individuals from [company name/university], from regulatory authorities or from the NHS Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records".

7. The Committee requests that a lay explanation is provided for 'verbatim' (i.e. word for word) in the PISs.

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 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).

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.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

There were no declarations of interest.

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

13/LO/0279 **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

PP

Dr Jan Downer
Chair

Email: nrescommittee.london-harrow@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*
"After ethical review – guidance for researchers"

Copy to: *Ms Meaghan Kall*
Ms Angela Williams, North Central London Research Consortium

NRES Committee London - Harrow

Attendance at Committee meeting on 12 March 2013

Committee Members:

Name	*Profession*	*Present*
Mr David Anderson-Ford	Director of Research Ethics and Governance	No
Mrs Veronika Bernstein	Translator	Yes
Mr Andrew Caunce	Chief Pharmacist	Yes
Mr Kevin Coughlan	Retired	Yes
Dr Jan Downer	Consultant Anaesthetist	Yes
Dr Annette Gilmore	Research Nurse	No
Miss Shelly Glaister-Young	Barrister	Yes
Dr Sanober Haq	Doctor of Medicine	Yes
Dr John Keen	General Practitioner	Yes
Ms Ann Malkin	Consultant Psychologist	No
Mr Graham Smith	Business Consultant	Yes
Mr Jim Wood	Retired IT Consultant	No

Also in attendance:

Name	*Position (or reason for attending)*
Miss Libby Watson	Committee Co-ordinator