



National Research Ethics Service

NORTH WEST 10 RESEARCH ETHICS COMMITTEE – GREATER MANCHESTER NORTH

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Dr Rebecca Harris
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23 July 2010

Dear Dr Harris

Study Title:	Contracting with General Dental Services
REC reference number:	10/H1011/38
Protocol number:	SP000415

Thank you for your letter of 20 July 2010, 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.

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

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.

For NHS research sites only, management permission for research ("R&D approval") should be obtained from the relevant care organisation(s) 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>.

This Research Ethics Committee is an advisory committee to North West Strategic Health Authority

The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

Where the only involvement of the NHS organisation is as a Participant Identification Centre (PIC), management permission for research is not required but the R&D office should be notified of the study and agree to the organisation's involvement. Guidance on procedures for PICs is available in IRAS. Further advice should be sought from the R&D office where necessary.

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
Investigator CV		01 June 2010
Protocol	1.0	01 June 2010
REC application	3.0	02 June 2010
Covering Letter	Email	20 July 2010
Letter from Sponsor		02 June 2010
Interview Schedules/Topic Guides	1	20 July 2010
Questionnaire	1	20 July 2010
Participant Information Sheet: Stakeholder interviews	1	01 June 2010
Participant Information Sheet: Patients	1	20 July 2010
Response to Request for Further Information	1	20 July 2010
Participant Information Sheet: Case studies Dental/Medical Practice	1	01 June 2010
Participant Information Sheet: PCT Commissioners.	1	01 June 2010
Participant Consent Form: Stakeholder interviews	1	01 June 2010
Participant Consent Form: Patients	1	20 July 2010
Participant Consent Form: Case studies Dental/Medical Practice	1	01 June 2010
Participant Consent Form: PCT Commissioners	1	01 June 2010
Evidence of insurance or indemnity		22 July 2009
Referees or other scientific critique report		22 February 2010

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

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.

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
- 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.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

10/H1011/38

Please quote this number on all correspondence

Yours sincerely


Dr Peter Stanley Klimiuk
Chair

Enclosures: "After ethical review – guidance for researchers" SL- AR2

Copy to: Mrs Lindsay Carter, University of Liverpool

Ms Gabrielle Marr, R&D office for Liverpool PCT