NHS
National Research Ethics Service
North West 9 Research Ethics Committee – Greater Manchester West
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25 March 2011

Professor Christopher Dowrick
Professor of Primary Medical Care
University of Liverpool
1st Floor Waterhouse Building B
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Dear Professor Dowrick

Study title:	**Research into implementation strategies to support patients of different originsand language background in a variety of European primary care settings**
REC reference:	**11/NW/0052**
Protocol number:	**UoL0000671**

Thank you for your letter of 22 March 2011, 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

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*
Protocol	1	15 September 2010
Letter of invitation to participant	1	16 November 2010
Response to Request for Further Information		22 March 2011
Participant Information Sheet: Service Provider	3	22 March 2011
REC application	3.1	24 January 2011
Copy of Unfavorable Opinion Letter		14 January 2011
Participant Information Sheet: Service User	3	22 March 2011
Evidence of insurance or indemnity	Clinical Trials Compensation Insurance (CLIN97UK06AN)	03 August 2010
Referees or other scientific critique report	RESTORE: Response to Evaluator's Comments	25 May 2010
Referees or other scientific critique report	External Assessment on Sampling Strategy	30 January 2011
Investigator CV	Christopher Dowrick	
Participant Consent Form	3	22 March 2011
Covering Letter		02 February 2011
Letter from Sponsor		26 November 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.

11/NW/0052	**Please quote this number on all correspondence**

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

Yours sincerely

pp

Dr Lorraine Lighton
Chair

Email: Shehnaz.ishaq@northwest.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

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