NHS
Health Research Authority

National Research Ethics Service

NRES Committee London - Fulham
[redacted]

23 January 2013

Professor Leone Ridsdale
Professor of Neurology and General Practice
King's College London
Institute of Psychiatry
[redacted]

Dear Professor Ridsdale

Study title:	**Self-Management education for adults with poorly controlled epILEpsy(SMILE): A project involving a randomised controlled trial.**
REC reference:	**12/LO/1962**
Protocol number:	**CSA/12/032**
IRAS project ID:	**112711**

Thank you for your letter of 18 January 2013, 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 Chairman.

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, Miss Shehnaz Ishaq, [redacted]

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.

The Committee pointed out that there is a typographical error on the Information Sheet; the heading 'What is the purpose of the study?' is listed as paragraph 8 when in fact it should be paragraph 1. The Committee strongly advise that this is corrected before sending out to participants.

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).

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

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*
Advertisement	Appendix C, Version 1.0	21 November 2012
Advertisement	Appendix C - version 1.1 - Advert for participants for External Pilot to be placed on British Epilepsy Association webpage and in user magazine	17 January 2013
Covering Letter		21 November 2012
Covering Letter		17 January 2013
Evidence of insurance or indemnity	Arthur J Gallagher International	30 July 2012

Evidence of insurance or indemnity	Gallagher Heath	01 August 2012
Evidence of insurance or indemnity	Zurich Municipal	20 July 2012
GP/Consultant Information Sheets	Appendix I, Version 1	21 November 2012
GP/Consultant Information Sheets	Appendix J, Version 1.0	21 November 2012
GP/Consultant Information Sheets	Appendix G - Letter from research team inviting patient to participate in Phase 2 RCT - Version 1.1	17 January 2013
Investigator CV	Professor Leone Ridsdale	21 November 2012
Letter of invitation to participant	Appendix E - Letter from consultant to patient seeking their permission for notes to be screened - version 1.1	17 January 2013
Other: Email regarding time of meeting		22 November 2012
Other: REC Form declaration page- CI signature	3.4	21 November 2012
Other: REC Form declaration page- Sponsor signature	3.4	21 November 2012
Participant Consent Form: Appendix D Participant Consent Form for External Pilot	1.0	21 November 2012
Participant Consent Form: Appendix H Consent Form for Randomised Controlled Trial	1.0	21 November 2012
Participant Information Sheet: Appendix A - External Pilot PIS phase 1	1.1	17 January 2013
Participant Information Sheet: Appendix B - PIS for phase 2 Randomised Controlled Trial	1.1	17 January 2013
Participant Information Sheet: Appendix F - ABBREVIATED version of Phase 2 RCT PIS to accompany letter from Consultant Neurologist	1.1	17 January 2013
Protocol	1.0	21 November 2012
Questionnaire: Appendix K - Validated Epilepsy Self Report Questionnaires to be used	QOLIE-31-P, Seizure Frequency, Psychological Distress, EUROQOL: EQ-5D, Mastery/Control, Medication Adherence, Health Service Use - CSRI, Felt Stigma, Impact	
REC application	3.4	21 November 2012
Referees or other scientific critique report	Reviewers" and Commissioners" comments and research team"s response	
Response to Request for Further Information		18 January 2013

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

12/LO/1962	**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

Signed on behalf of:
Dr Charles Mackworth-Young
Chairman

Email:nrescommittee.london-fulham@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Ms Jenny Liebscher, King's College London

Dr Zoe Harris, King's College Hospital

Dr Adam Noble, King's College London