NHS
National Research Ethics Service

South West 2 Research Ethics Committee
Royal Devon & Exeter Hospital (Heavitree)
Room TH5
Gladstone Road
Exeter
Devon
EX1 2ED

Telephone: 01392 405272
Fax: 01392 405270
Email: Southwest.REC@nhs.net
www.nres.npsa.nhs.uk

14 September 2010

Dr Esther Crawley
Senior Lecturer
University of Bristol
Centre for Child and Adolescent Health
Hampton House
Cotham Hill
Bristol
BS6 6JS

Dear Dr Crawley

Full title of study: **Assessing the feasibility and acceptability of comparing the Lightning Process? with specialist medical care for Chronic Fatigue Syndrome or Myalgic Encephalopathy (CFS/ME) - pilot Randomized Controlled Trial.**

REC reference number: **10/H0206/32**

Thank you for your letter of 13 September 2010. I can confirm the REC has received the documents listed below as evidence of compliance with the approval conditions detailed in our letter dated 08 September 2010. Please note these documents are for information only and have not been reviewed by the committee.

Documents received

The documents received were as follows:

Document	Version	Date
Participant Information Sheet: Information Leaflet for Parents	7	01 September 2010
Participant Information Sheet: Information Leaflet for Teenagers	6	01 September 2010

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

10/H0206/32	Please quote this number on all correspondence

Yours sincerely

Mrs Barbara Inger
Committee Co-ordinator

E-mail: Southwest.REC@nhs.net

Copy to: Dr Jane Carter

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08 September 2010

Dr Esther Crawley
Senior Lecturer
University of Bristol
Centre for Child and Adolescent Health
Hampton House
Cotham Hill
Bristol
BS6 6JS

Dear Dr Crawley

Study Title: **Assessing the feasibility and acceptability of comparing the Lightning Process? with specialist medical care for Chronic Fatigue Syndrome or Myalgic Encephalopathy (CFS/ME) - pilot Randomized Controlled Trial.**

REC reference number: **10/H0206/32**

Thank you for your letter of 20 August 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.

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.

Other conditions specified by the REC

PALS details should be inserted into the Teenager PIS as with the adult version as some 16 year olds may want to approach them independently.

The information sheet for parents has a typo at the third point in part 1 also throughout "You" and "Your child" seem to be used inconsistently.

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).

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.

Approved documents

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

Document	Version	Date
Investigator CV		10 May 2010
Protocol	6	28 July 2010
Interview topic guide	2	10 May 2010
Phil Parker - Training Assessment Form	2	28 July 2010
Certificate of Professional Liability Insurance		
GP Letter	1	10 May 2010
REC application	2.5	24 May 2010
Covering Letter		24 May 2010
Covering Letter		28 July 2010
Participant Information Sheet: Information Leaflet for Parents	6	20 August 2010
Participant Consent Form: Parent Consent to study	3	10 May 2010
Participant Consent Form: Parental Consent to child interview	3	10 May 2010

Participant Consent Form: Teenagers Consent to study	4	20 August 2010
Response to Request for Further Information		28 July 2010
Response to Request for Further Information		20 August 2010
Participant Information Sheet: Information Leaflet for Teenagers	6	20 August 2010
Participant Consent Form: Teenager Consent to interview	5	20 August 2010
Participant Consent Form: Child Consent to study	4	01 July 2010
Participant Consent Form: Child Consent to contact	4	01 July 2010
Participant Consent Form: Parental Consent to contact	3	10 May 2010
Participant Consent Form: Parental Consent to interview	3	10 May 2010
Participant Consent Form: Consent to record intervention	4	01 July 2010
Participant Consent Form: Teenager Consent to contact	4	01 July 2010
Questionnaire: Work Productivity and Activity Impairment	2	
Questionnaire: SF-36		
Questionnaire: Health Resource Use Questionnaire	1	10 May 2010
Flow Chart		
Check List		24 May 2010
Grant Letter		24 November 2009
Confirmation of Grant		08 March 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/H0206/32	Please quote this number on all correspondence

Yours sincerely

pp

Mr Richard Ashby
Chair

Email: Southwest.REC@nhs.net

Enclosures: "After ethical review – guidance for researchers" [SL-AR1 for CTIMPs, SL- AR2 for other studies]

Copy to: Dr Jane Carter