South West 2 REC
c/o Assembly Rooms
UH Bristol Trust Headquarters
Marlborough Street
Bristol
BS1 3NU

Tel: 0117 342 3613

14 June 2010

Dr Esther Crawley
Senior Lecturer
University of Bristol
Centre for Child and Adolescent Health
Hampton House
Cotham Hill
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**
Protocol number:	**Version 5**

Thank you for your application for ethical review, which was received on 14 June 2010. I can confirm that the application is valid and will be reviewed by the Committee at the meeting on 08 July 2010.

Meeting arrangements

The meeting will be held in the The Devon Hotel, Matford, Exeter By Pass, Exeter, EX2 8XU on 08 July 2010. The Committee would find it helpful if you could attend the meeting between1pm and 1.45 pm to respond to any questions from members. Other key investigators and a representative of the sponsor are also welcome to attend. This may avoid the need to request further information after the meeting and enable the Committee to make a decision on the application more quickly.

If you have a disability and need any practical support when attending the REC meeting you may wish to contact the REC office so appropriate arrangements can be made if necessary.

Please note that it is difficult to be precise about the timing as it will depend on the progress of the meeting. We would kindly ask you to be prepared to wait beyond the allocated time if necessary.

Committee meetings are occasionally attended by observers, who will have no vested interest in the applications under review or take any part in discussion. All observers are required to sign a confidentiality agreement.

Documents received

The documents to be reviewed are as follows:

Document	Version	Date
Covering Letter		24 May 2010
REC application	2.5	24 May 2010
Protocol	5	10 May 2010
Investigator CV		10 May 2010
Check List		24 May 2010
Participant Information Sheet: Information Leaflet for Parents	4	10 May 2010
Participant Information Sheet: Information Leaflet for Teenagers	4	10 May 2010
Participant Consent Form: Parental Consent to contact	3	10 May 2010
Participant Consent Form: Parent Consent to study	3	10 May 2010
Participant Consent Form: Parental Consent to interview	3	10 May 2010
Participant Consent Form: Parental Consent to child interview	3	10 May 2010
Participant Consent Form: Consent to record intervention	3	10 May 2010
Participant Consent Form: Teenager Consent to interview	3	10 May 2010
Participant Consent Form: Teenager Consent to contact	3	10 May 2010
Participant Consent Form: Teenagers Consent to study	3	10 May 2010
Participant Consent Form: Child Consent to study	3	10 May 2010
Participant Consent Form: Child Consent to contact	3	10 May 2010
Interview topic guide	2	10 May 2010
Questionnaire: Work Productivity and Activity Impairment	2	
Questionnaire: Health Resource Use Questionnaire	1	10 May 2010
Questionnaire: SF-36		
Phil Parker - Training Assessment Form		20 May 2010
Certificate of Professional Liability Insurance		
Flow Chart		
Grant Letter		24 November 2009
Confirmation of Grant		08 March 2010
GP Letter	1	10 May 2010

No changes may be made to the application before the meeting. If you envisage that changes might be required, we would advise you to withdraw the application and re-submit it.

Notification of the Committee's decision

You will receive written notification of the outcome of the review within 10 working days of the meeting. The Committee will issue a final ethical opinion on the application within a maximum of 60 days from the date of receipt, excluding any time taken by you to respond fully to one request for further information or clarification after the meeting.

R&D approval

All researchers and local research collaborators who intend to participate in this study at sites in the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland should apply to the R&D office for the relevant care organisation. A copy of the Site-Specific Information

(SSI) Form should be included with the application for R&D approval. You should advise researchers and local collaborators accordingly.

The R&D approval process may take place at the same time as the ethical review. Final R&D approval will not be confirmed until after a favourable ethical opinion has been given by this Committee.

Guidance on applying for R&D approval is available at http://www.rdforum.nhs.uk/rdform.

There is no requirement for separate Site-Specific Assessment as part of the ethical review of this research. The SSI Form should not be submitted to local RECs.

Communication with other bodies

All correspondence from the REC about the application will be copied to the research sponsor. It will be your responsibility to ensure that other investigators, research collaborators and NHS care organisation(s) involved in the study are kept informed of the progress of the review, as necessary.

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

Yours sincerely

B Inger

Mrs Barbara Inger
Committee Co-ordinator

Telephone: 01392 405272
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Email: Southwest.REC@nhs.net

Enclosure: Directions to meeting venue

Copy to: Dr Jane Carter