

NRES Committee South West - Exeter

Bristol Research Ethics Committee Centre
Whitefriars
Level 3
Block B
Lewins Mead
Bristol
BS1 2NT

Tel: 0117 342 1332
Fax: 0117 342 0445
e-mail: Ubh-tr.SouthWest2@nhs.net

13 September 2012

Dr Esther Crawley
Senior Lecturer
University of Bristol
Centre for Child and Adolescent Health
Hampton House
Cotham Hill
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: 10/H0206/32

Amendment number: 2

Amendment date: 20 August 2012

The above amendment was reviewed at the meeting of the Sub Committee held on 06 September 2012.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Letter to school	v2 - clean copy	03 May 2012
Letter to school	v2 - tracked changes	03 May 2012
GP/Consultant Information Sheet	v3 - clean copy	03 May 2012
GP/Consultant Information Sheets	v3 - tracked changes	03 May 2012
Participant Consent Form	v5 - clean copy	16 May 2012
Participant Consent Form	v5 - tracked changes	16 May 2012
Participant Information Sheet: For parents	v11 - clean copy	08 May 2012

Participant Information Sheet: For parents	v11 - tracked changes	08 May 2012
Participant Information Sheet: For teenagers	v11 - clean copy	03 May 2012
Participant Information Sheet: For teenagers	v11 - tracked changes	03 May 2012
Protocol	12 - tracked changes	01 August 2012
Notice of Substantial Amendment (non-CTIMPs)		20 August 2012
Covering Letter		30 August 2012
Protocol	12 - clean copy	01 August 2012
Participant Consent Form: Teenagers consent to study	6 - clean copy	16 May 2012
Participant Consent Form: Teenagers consent to study	6 - tracked changes	16 May 2012
Participant Consent Form: Coinsent to contact form	5 - clean copy	16 May 2012
Participant Consent Form: Consent to contact form	5 - tracked changes	16 May 2012
Participant Consent Form: Teenager (12 to 18) consent/assent to interview	6 - clean copy	16 May 2012
Participant Consent Form: Teenager (12 to 18) consent/assent to interview	6 - tracked changes	16 May 2012
Participant Consent Form: Assent to contact for under 16s	5 - clean copy	16 May 2012
Participant Consent Form: Assent to contact for under 16s	5 - tracked changes	16 May 2012
Participant Consent Form: Under 16 Assent to study	6 - clean copy	16 May 2012
Participant Consent Form: Under 16 Assent to study	6 - tracked changes	16 May 2012
Participant Consent Form: Parentla consent to child interview	4 - clean copy	16 May 2012
Participant Consent Form: parental consent to child interview	4 - tracked changes	16 May 2012
Participant Consent Form: Parental consent to contact form	4 - clean copy	16 May 2012
Participant Consent Form: Parental consent fo contact form	4 - tracked changes	16 May 2012
Participant Consent Form: Parental consent to study form	4 - clean copy	16 May 2012
Participant Consent Form: Parental consent to study form	4 - tracked changes	16 May 2012
Participant Consent Form: Parental consent to parental interview	4 - clean copy	16 May 2012
Participant Consent Form: Parental consent to parental interview	4 - tracked changes	16 May 2012

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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.

10/H0206/32:

Please quote this number on all correspondence

Yours sincerely

Kristin Peck

pp **Dr Denise Sheehan**
Chair
NRES Committee South West - Exeter

Enclosures:

List of names and professions of members who took part in the review

Copy to:

Dr Jane Carter, RNHRD

NRES Committee South West - Exeter

Attendance at Sub-Committee of the REC meeting on 06 September 2012

<i>Name</i>	<i>Profession</i>	<i>Capacity</i>
Dr Lee Burton	GP	Expert
Dr Denise Sheehan	Consultant Oncologist	Expert