



National Research Ethics Service
NRES Committee South West - Exeter

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01 June 2011

Dr Esther Crawley
Senior Lecturer
University of Bristol
Centre for Child and Adolescent Health
Hampton House
Cotham Hill
Bristol
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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: 1

Amendment date: 17 May 2011

The above amendment was reviewed at the meeting of the Sub-Committee held on 31 May 2011.

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
GP/Consultant Information Sheets	2	17 January 2011
Participant Information Sheet: Teenagers Consent to Study	5	16 May 2011
Participant Information Sheet: Parent Information Sheet	10	16 May 2011
Participant Information Sheet: Patient Information Sheet	9	16 May 2011
Protocol	7	16 May 2011

Notice of Substantial Amendment (non-CTIMPs)	1	17 May 2011
Covering Letter	e-mail	17 May 2011
Participant Consent Form: Child Assent to Study Form	5	16 May 2011
Participant Consent Form: Parent Consent to Study Form	4	16 May 2011

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 (July 2001) 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
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Yours sincerely



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 31 May 2011

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