



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
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: 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

Kirsten Peck

pl **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

Royal National Hospital for Rheumatic Diseases



NHS Foundation Trust

Upper Borough Walls
Bath. BA1 1RL

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20th October 2011

Debbie Johnson
Centre for Child and Adolescent Health
School of Social and Community Medicine
Oakfield House, Oakfield Grove
Bristol BS8 2BN

Dear Debbie

Title: Specialist Medical Intervention and Lightning Evaluation

Thank you for your notification of amendments to the above project which was considered at the R&D Committee meeting on 18th October 2011. I am pleased to inform you that the R&D Committee approved the amendments which consist of:

Fax dated 9/6/2011

Teenagers consent to study: SMILE

Inclusion of 'If I do not return follow up forms, I agree for a researcher to contact me on the phone to find out how I am getting along.


Yours sincerely

Jane Carter
R&D Manager
on behalf of the R&D Committee



RNHRD NHS FT Data Protection Act Research Form

R& D Reference:	<i>Office use only</i>	Principal Investigator/ Lead Researcher:	Dr Esther Crawley
Title of Research Project:	Assessing the feasibility and acceptability of comparing the Lightning Process® with specialist medical care for Chronic Fatigue Syndrome or Myalgic Encephalopathy (CFS/ME) - pilot Randomised Controlled Trial.		
Length of Project:	Months	10	Years 1
Source of Data:	<input checked="" type="checkbox"/> Patient	<input checked="" type="checkbox"/> Staff	<input checked="" type="checkbox"/> Other – Please specify:
	Almost all of the data will be from patients. However, interventions will be recorded so small amounts of data will exist in anonymised transcripts from staff and Lightning practitioners delivering the interventions.		
Organisation involved in Research:	<input checked="" type="checkbox"/> RNHRD NHS FT	<input checked="" type="checkbox"/> University of Bristol	<input checked="" type="checkbox"/> Other – Please specify: Lightning Process
	Two members of the Lightning Process Executive are co-applicants for this study.		
Purpose of Research:	The overall aim of this study is to investigate the feasibility and acceptability of conducting a Randomised Controlled Trial (RCT) to investigate the effectiveness and cost-effectiveness of specialist medical care with specialist medical care plus the Lightning Process in treating CFS/ME in children. The specific objectives aim to inform the design of a full-scale, adequately powered randomised trial.		
Who is the research data/information going to be shared with?	Other NHS Organisations <input type="checkbox"/> , RNHRD Staff <input type="checkbox"/> , Private Company <input type="checkbox"/> University staff / University students <input checked="" type="checkbox"/> Other (please state):		
Please state type of data (e.g. computer database, paper records, video, audio photographs blood/urine samples), storage location during project.	<p>Types of data being collected: 1. Questionnaire data, 2. Data collected from interview</p> <p>Storage of data location/s: Personal data will be stored on the RNHRD computer. The 13 digit ID number will be linked to personal data in this way. Once consent forms are signed, these will be kept in a locked filing cabinet, in a locked office, within another locked office at the University of Bristol.</p> <p>Questionnaire data will be stored on an encrypted password protected university server. Interview transcripts will be anonymised and then stored on an encrypted, password protected university server.</p> <p>All laptops and memory sticks are encrypted. All data is anonymised at source and no identifying information is kept with data on questionnaires.</p> <p>Proposed secure Protection of Data e.g. laptops, memory sticks security, paper file storage</p>		
How do you assure subjects about confidentiality of their information? Please attach Patient Information Sheet:	We have details of the anonymisation on the patient information sheets attached. We also include details of how data is stored on every consent form, a copy of which is kept by patients.		
How will the research data be securely protected, stored and destroyed at the end of the study?	Where is the proposed Secure storage of data; how and for how long? Transcripts will be anonymised and kept on a secure university encrypted password protected university server for five years. The data will be wiped by IT after 5 years. The memory sticks used for the interviews will be destroyed once the anonymised transcript has been put on to the university server.		

	No research data will be kept at the RNHRD. How will data be destroyed at the end of the study?				
Is the information being sent outside of the UK?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Will patient consent be obtained?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Is the information being sent outside of the EU?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Will patient consent be obtained?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Will patient case-notes be used?	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Will patient consent be obtained?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
I will ensure my Research project is compliant with the Data Protection Act, the Department of Health Code of Confidentiality and the RNHRD's code of conduct for employees in respect of confidentiality:					
Signature:			Print Name and Date:	CRAWLEY 26/5/2010	
Recommendations			Signature and date of DPA Lead		

NB: Double click left mouse button to 'check' boxes.