



National Research Ethics Service

South West Research Ethics Committee

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13 August 2010

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

Protocol number: Version 5

Thank you for your letter of 28 July 2010, responding to the Committee's request for further information on the above research, and enclosing the following revised documents:

The further information and revised documentation has been considered on behalf of the Committee by named member(s) of the REC.

You are to be congratulated on giving consideration to answering all our concerns in your letter and in most cases making the changes. Where changes have not been made a detailed explanation has been given.

However, the Committee would be grateful for a more complete response on the following points

Information Sheet for Teenagers version 5 July 2010:

This is still not suitable for 12 year olds in particular:

1. It says they will contact schools to see how the children have been and it needs to say 'with your permission'.
2. The flow chart refers to 'your child' and should say 'you'.

This Research Ethics Committee is an advisory committee to South West Strategic Health Authority

The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England

3. Under the section entitled 'What if I have a problem?' It includes the fact that they will have to pay their own legal costs. It is suggested that this whole section needs changing to make it acceptable to teenagers.
4. It also says after the above section 'all staff have had appropriate police checks' it is thought that not all teenagers will know what this refers to or why it is important and should be explained.

Teenager 12/18 consent assent form version 4 July 2010:

5. Statement 2 should add 'I know I can withdraw from this study at any time **without giving a reason**'

Flow charts:

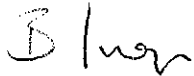
6. These are over complicated for a lay person and no attempt has been made to simplify or address technical information.
7. The headings within the chart are identical and do not show the Lightning Group

When submitting your response to the Committee, please send revised documentation where appropriate underlining or otherwise **highlighting** the changes you have made and ~~striking through~~ any deletions, giving revised version numbers and dates.

The 60 day clock for issue of a final ethical opinion on this application will re-start when the Committee has received a response on the outstanding points.

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

Yours sincerely



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Committee Co-ordinator

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Copy to: Dr Jane Carter