

20th August 2010

REC reference number 10/H0206/32

Dear Mr Ashby,

Thank you for the feedback received from the South West Research Ethics committee dated 13th of August. We are grateful for the further points raised which we feel will further improve this study.

We have answered the questions raised by the Ethics committee and enclose the documents with tracked changes. We are unable to track changes in the flow chart but have detailed the changes made in this letter and we hope this is sufficiently clear.

A table at the end of this letter lists the documents changed with their new name, version number and date as applicable.

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”.**

We have added “with your permission” to paragraph 3, page 4 which now reads “We will ask your school with your permission about”

- 2. The flow chart refers to “your child” and should say “you”.**

We have changed “is child eligible for study?” to “eligible for study?”

- 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.**

We have changed “due to someone’s negligence” to “due to someone being careless” and “may have grounds for legal action for compensation against the RNHRD” to “may be able to take legal action to get repayment from the hospital” and “but you may have to pay your legal costs” to “but your parents may need to pay a lawyer to help you”. We

have also changed “the normal National Health Service complaints mechanism will still be available to you (if appropriate)” to “you can also use the normal National Health Service system for complaints if you want to.

- 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.**

We have added the following: “All those working in the study have had the necessary police checks to make sure they are safe to work with children and young people.”

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”**

We have added “without giving a reason”

- 6. These are over complicated for a lay person and no attempt has been made to simplify or address technical information**

We have deleted eligibility criteria as only those who are eligible will be given the information sheets and we have deleted N=48 from each arm as this is technical information. We have changed “assessment” to “at clinic assessment” and “consent to study” in the first box to “consent to contact” as well as “consent to randomisation” to “consent to study” as this is consistent with the consent forms. We have changed “outcomes measured” to “questionnaires received”.

- 7. The headings within the chart are identical and do not show the Lightning Group**

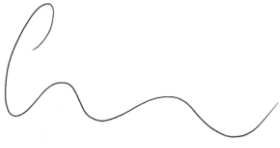
We have added plus lightning process to the heading for the arm that has the Lightning process added on. This now reads “Specialist CFS/ME treatment plus Lightning Process”

Please find below a table listing the original and revised version numbers and dates of the documentation that has been changed in the order listed your original letter:

Leaflet	Version	Date	New version	New date
Information leaflet for teenagers	v5	July 2010	V6	August 2010
Information leaflet for parents	V5	July 2010	V6	August 2010
Teenager (12 to 18) consent/assent to teenager interview	v4	July 2010	V5	August 2010

Thank you again for considering this study and for the Ethics Committee’s input in improving this study.

Yours

A handwritten signature in black ink, appearing to be 'E. Crawley', written in a cursive style.

Esther Crawley

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