

## South West - Frenchay Research Ethics Committee

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29 January 2016

Dr Jane Carter  
 Royal United Hospital Foundation Trust- RNHRD  
 Upper Borough Walls  
 Bath  
 BA1 1RL

Dear Dr Carter

**Study title:** **The feasibility and acceptability of conducting a trial investigating the effectiveness and cost effectiveness of Graded Exercise Therapy compared to Activity Management for paediatric CFS/ME: A feasibility randomised controlled trial**

**REC reference:** **15/SW/0124**

**Amendment number:** **1. 18/11/2015**

**Amendment date:** **18 November 2015**

**IRAS project ID:** **176764**

The above amendment was reviewed by the Sub-Committee in correspondence.

### 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.

This amendment sought approval for the following changes :

Consent to contact forms: wording had been altered to make the forms more precise as well as requested proof of DoB. Participants aged 16-17 do not need parents to consent on their behalf, however parents would be asked to complete parental questionnaires and do need to provide consent to this research procedure. The intent to use data collected during the feasibility study for the full scale trial, point has now been added to PCF.

Consent to discussion: Addition of Clearer instruction on how to complete the form, the parental consent box has been removed from the 16-17 consent form and overall made more child friendly.

### Approved documents

The documents reviewed and approved at the meeting were:

| <i>Document</i>  | <i>Version</i>   | <i>Date</i>      |
|--|------------------|------------------|
| Notice of Substantial Amendment (non-CTIMP)                  | 1.<br>18/11/2015 | 18 November 2015 |
| Participant consent form [ 8-15 assent to contact ]          | d06              | 11 August 2015   |
| Participant consent form [ 8-15 assent to contact ]          | d07              | 18 November 2015 |
| Participant consent form [ 8-15 assent to record discussion] | d07              | 18 November 2015 |

|   |     |                  |
|---|-----|------------------|
| Participant consent form [ 16-17 consent to contact]          | d07 | 18 November 2015 |
| Participant consent form [16-17 consent to record discussion] | d07 | 18 November 2015 |
| Participant consent form [16-17 consent to study ]            | d06 | 18 November 2015 |
| Participant consent form [parent carer consent to contact ]   | d07 | 18 November 2015 |
| Participant consent form [parent carer consent to study]      | d06 | 18 November 2015 |
| Research protocol or project proposal                         | 1.1 | 18 November 2015 |

## 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.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

|                    |   |
|--------------------|---|
| <b>15/SW/0124:</b> | <b>Please quote this number on all correspondence</b> |
|--------------------|---|

Yours sincerely



**Mr Stephen Draper**  
Chair

E-mail: [nrescommittee.southwest-frenchay@nhs.net](mailto:nrescommittee.southwest-frenchay@nhs.net)

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

*Copy to: Dr Jane Carter, Royal United Hospital Foundation Trust- RNHRD  
Dr Esther Crawley, University of Bristol*

## South West - Frenchay Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 15 February 2016

### Committee Members:

| <i>Name</i>       | <i>Profession</i>    | <i>Present</i> |
|-------------------|----------------------|----------------|
| Mr Stephen Draper | Retired Head teacher | Yes            |
| Mr Jeremy Ruddock | Osteopath            | Yes            |

### Also in attendance:

| <i>Name</i>         | <i>Position (or reason for attending)</i> |
|---------------------|---|
| Miss Lidia Gonzalez | REC Assistant                             |