



Health Research Authority

South West - Frenchay Research Ethics Committee

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27 July 2016

Dr Esther Crawley
Consultant Paediatrician, Reader in Child Health
University of Bristol
School of Social and Community Medicine
Oakfield House, Oakfield Grove
Bristol
BS8 2PS

Dear Dr Crawley

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: 3. 16/06/2016

Amendment date: 16 June 2016

IRAS project ID: 176764

The above amendment was reviewed at the meeting of the Sub-Committee held on 25 July 2016 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.

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)		16 June 2016
Other [HealthEconomics 6 month]	2.0	16 June 2016
Other [HealthEconomics 12 month]	2.0	16 June 2016
Other [HealthEconomics Baseline]	2.0	16 June 2016
Other [Cambridge closedown_Report]		01 July 2016
Research protocol or project proposal	3.0	16 June 2016

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/>

15/SW/0124:	Please quote this number on all correspondence
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Yours sincerely

p.p. Aisha Glen

Miss Wendy Bertram
Chair

E-mail: 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

South West - Frenchay Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 25 July 2016

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Paul Allen	Consultant Oral Surgeon	Yes	
Miss Wendy Bertram	Orthopaedic Research Fellow	Yes	

Also in attendance:

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