Cambridgeshire Community Services NHS
NHS Trust

15th January 2016

Dr David Vickers
Cambridgeshire Community Services NHS Trust
Unit 3, Meadow Lane, St Ives
Cambridge
PE27 4LG

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Lockton House
Clarendon Road
Cambridgeshire
CB2 8FH
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Direct dial: 01223 725466

Dear Dr Vickers,

Re: MAGENTA-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

Re: L01458 /CSP176764

Your proposal has been reviewed by the Medical Director of Cambridgeshire Community Services NHS Trust.

I am pleased to inform you that Cambridgeshire Community Services NHS Trust has given permission for the following research to take place.

This permission is subject to the enclosed standard terms and conditions and conditional upon you notifying the research governance team of any changes to the study-related paperwork.

Members of the research team who are not employed by the Trust must have appropriate substantive or honorary research contracts or letters of access with the Trust prior to commencing work on the study, additional researchers who join the study post approval must also hold a suitable contract or letter of access before they start.

Unless we hear from you within a month of this letter, we will assume that you are abiding by these conditions.

The project must follow the agreed protocol and be conducted in accordance with Trust policy and procedures in particular in regard to data protection, health & safety and information governance standards. The research team are required to follow the reasonable instructions of the research site manager and can contact the RMG office for RMG advice or the Trust RMG lead in relation to queries on local policy.

On completion of clinical trials of interventional medicinal products/devices participants need to be aware that local Trust prescribing policy and formulary applies therefore participants cannot expect to continue on the research trial product/device on completion of the trial.

Approval is subject to adherence to the Data Protection Act 1998, NHS Confidentiality Code of Practice, the Human Tissue Act 2004, the NHS Research Governance Framework for Health and Social Care, (2nd edition) April 2005, the Mental Capacity Act and any further legislation released during the time of this study. Approval for Clinical Trials is on the basis that they are

conducted in accordance with European Union Directive and the Medicines for Human Use (Clinical Trials) Regulations 2004 principles, guidelines and later revisions, and in accordance ICH Good Clinical Practice.

You will be required to complete monitoring information during the course of the research, as requested by the RMG office. Cambridgeshire Community Services NHS Trust reserves the right to withdraw research management approval for a project if researchers fail to respond to audit and monitoring requests.

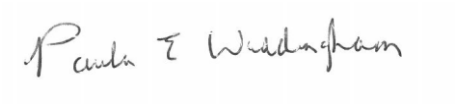
Should any adverse incidents occur during the research, Cambridgeshire Community Services NHS Trust Incident and Near Miss Reporting Policy should be used, the RMG Office informed and incident procedures adhered to at the research site.

If you make any amendments to your project, please ensure that these are submitted to the research ethics committee and the RMG office and that any changes are not implemented until approval has been received.

We welcome feedback about your experience of this review process to help us improve our systems. May I take this opportunity to wish you well with your research and we look forward to hearing the progress and outcomes for the study.

Please contact the RMG team should you have any queries.

Yours sincerely,



Paula Waddingham
Senior Research Fellow
Cambridgeshire Community Services NHS Trust