The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

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Newcastle upon Tyne
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SR/MW/ED

26 January 2016

Dr Caroline Grayson
Consultant Paediatrician
Great North Children's Hospital
RVI
Queen Victoria Road
Newcastle upon Tyne
NE1 4LP

Dear Dr Grayson,

Trust R&D Project:	**7551**
Title of Project:	**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**
Principal Investigator:	**Dr Caroline Grayson**
Number of patients:	**8**
Funder:	**National Institute for Health Research Health Technology Assessment**
Sponsor:	**Royal United Hospital Bath NHS Trust**
REC number:	**15/SW/0124**
IRAS Project Code:	**176764**
First participant to be recruited by:	**25/02/2016**

After completing the necessary risk and site assessments for the above research project, The Newcastle upon Tyne Hospitals NHS Foundation Trust grants NHS Management Permission for this research to take place at this Trust dependent upon:

(i) you, as Principal Investigator, agreeing to comply with the Department of Health's Research Governance Framework for Health and Social Care, and confirming your understanding of the responsibilities and duties of Principal Investigators by signing the Investigator Responsibilities Document. A copy of this document will be kept on file within the Joint Research Office.

(ii) you, as Principal Investigator, ensuring compliance of the project with all other legislation and guidelines including Caldicott Guardian approvals and compliance with the Data Protection Act 1998, Health and Safety at Work Act 1974, any requirements of the MHRA (*eg* CTA, EudraCT registration), and any other relevant UK/European guidelines or legislation (*eg* reporting of suspected adverse incidents).

(iii) where applicable, you, as Principal Investigator, should also adhere to the GMC supplementary guidance *Good practice in research* and *Consent to research* which sets out the good practice principles that doctors are expected to understand and follow if they are involved in research – see http://www.gmc-uk.org/guidance/ethical_guidance/5991.asp

The NIHR requires NHS organisations to recruit patients to CLRN Portfolio studies within 30 days from the date of this letter. The 30 day deadline for recruiting the first patient is therefore 25/02/2016.

Please note: the Department of Health 70 day bench mark requires recruitment within 70 days of a valid SSI submission. Therefore, recruiting within the NIHR 30 day target will ensure compliance with both targets.

NHS Permission applies to the research described in the protocol and related documentation as listed on the favourable ethical opinion(s) from NRES Committee South West - Frenchay, dated 03 July 2015. Specifically, the following versions of the key documents are approved:

Document	Version	Date
Research protocol or project proposal	v0.9	09 April 2015
Participant information sheet (PIS) [MAGENTA PIS Parent OR Carer]	v0.7	17 May 2015
Participant information sheet (PIS) [8-11]	v0.6	30 March 2015
Participant information sheet (PIS) [MAGENTA PIS 12-17]	v0.8	17 May 2015
Participant consent form [MAGENTA parent carer consent to study]	d0.5	17 May 2015
Participant consent form [MAGENTA 16-17 consent to study]	d0.5	17 May 2015
Participant consent form [Parent/Carer consent to contact]	d0.5	09 March 2015
Participant consent form [Parent/Carer consent to record]	d0.6	16 April 2015
Participant consent form [16-17 consent to record treatment session]	d0.5	09 March 2015
Participant consent form [16-17 consent to contact]	d0.5	09 March 2015
Participant consent form [16-17 consent to record]	d0.6	16 April 2015
Participant consent form [8-15 assent to study]		
Participant consent form [8-15 assent to record treatment session]		
Participant consent form [8-15 assent to record]	d0.6	16 April 2015
Participant consent form [8-15 assent to contact]		
Validated questionnaire [Sleep diary]	April 2015	
GP/consultant information sheets or letters [Letter to participants GP]	d0.1	09 April 2015
Validated questionnaire [Paediatrics follow-up postal assessment (under 12's)]		
Validated questionnaire [Paediatrics follow-up postal assessment (over 12's)]		
Validated questionnaire [MAGENTA Postal questionnaire pack over 12's]	v0.1	20 April 2015
Validated questionnaire [MAGENTA Postal questionnaire pack under 12's]	v0.1	20 April 2015
Other [CFSActivityRestSleepdiary.]		
Interview schedules or topic guides for participants [MAGENTA discussion topic guide]	d0.2	17 April 2015

Any changes to these documents, or any other amendments to the study must be submitted to the Research Ethics Committee and MHRA (if relevant) for review – see http://www.nres.npsa.nhs.uk/applications/after-ethical-review/amendments/ for guidance). All amendments must be submitted to the R&D office for review in parallel with ethical and regulatory review so that implications of the amendment can be assessed. You must send a copy of all amendment documents to the R&D office and if the changes or amendments to the study have implications for costs or use of resources, you must also submit details of these changes.

It is the Principal Investigator's responsibility to ensure that all staff involved in the research have Honorary Research Contracts or the necessary Letters of Access. These must be issued prior to commencing the research.

In addition, unless otherwise agreed with the Trust, the research will be covered for negligence under the CNST (Clinical Negligence Scheme for Trusts), however cover for no-fault harm is the responsibility of the Principal Investigator to arrange if required.

Please also note that for any NHS employee who generates Intellectual Property *in the normal course of their duties*, it is recognised that the Intellectual Property Rights remain with the employer and not the employee.

Yours sincerely

Susan Ridge
Research Governance Manager

CC: Finance Research and Development Team, Finance Department, Level 2, Regent Point
Michael McKean, Clinical Director
Esther Crawley, Chief Investigator
Jane Carter, Sponsor Representative
Clare Simmister, Research Team Lead
Debs Jackson, Trial Co-ordinator