

Royal National Hospital   
for Rheumatic Diseases

NHS Foundation Trust

Upper Borough Walls  
Bath, BA1 1RL

R&D Telephone: 01225 465941 x210  
Safe Haven fax: 01225 473461

**To whom it may concern**

SW REC 2

18<sup>th</sup> November 2010

**Re: REC review of SMILE project – Chief Investigator Dr Esther Crawley.**

Thank you for giving the RNHRD the opportunity to comment on this review.

As sponsor for this project under the Research governance framework the Trust would like to reiterate its support for this project which was approved, conditional upon full ethics approval, on June 16<sup>th</sup> 2010 by the R&D committee. After consideration of the recent issues raised in letters/correspondence asking for a review of the ethics decision the Trust R&D committee have considered the matter and wish to continue sponsorship of the project (again conditional upon ethical approval remaining in place). The Trust welcome the comprehensive information prepared by the research team in answer to the matters raised in the correspondence and would like to note the following:

The Trust feels that the research team have justified the need for the project to be carried out in children and that the project is within guidelines issued by national organisations and that a clear consent procedure is in place.

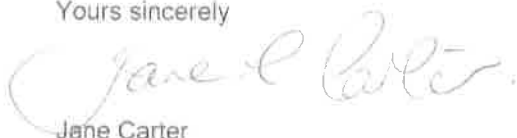
The Trust welcomes changes to the Patient information sheet which clarify that the Lightning Process (LP) is a training programme and that the practitioners delivering this training are not required to be clinically trained ie doctor, nurse, AHP.

The Trust welcomes the response from Mr Philip Parker acknowledging that the carrying out of this study or the results of this feasibility study do not confer any evidence for the efficacy of the LP and will not be used for promotional purposes.

We note that information has been provided about the care of children if there is an adverse response to the LP and that existing clinical care pathways will be followed and reporting will be in line with Good Clinical Practice guidelines and the Trust Incident and Risk Reporting Policy

We understand that the project will consider the outcome measures which will be utilised in any future trial (if supported by the feasibility project) and support this as it is important to effectively demonstrate clinical and patient relevant outcomes.

Yours sincerely



Jane Carter

Research and Development Manager on behalf of the RNHRD R&D Committee