

Royal National Hospital **NHS**
for Rheumatic Diseases

NHS Foundation Trust

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17th September 2012

Dr Esther Crawley
RNHRD

Dear ~~Rob~~ *Esther*

RBB 332 (SMILE) –Assessing the feasibility and acceptability of comparing the Lightning Process with Specialist Medical Care for CFS/ME – Pilot randomised controlled trial

Amendment 02, August 2012

Thank you for your notification of the substantial amendments to the above project which consist of:-

- Changes to all patient information sheets
- Interviews re: study process have now been stopped
- Integrated study has now been stopped and removed from all study documentation
- Set up of data monitoring committee
- Opt-out letter to be sent to participants to ensure they are happy their data is used for the full study
- Changes to outcome measures used in the study
- Changes to protocol to reflect all amendments
- Changes to Consent/assent forms

I am pleased to inform you that the amendments were reviewed by the R&D committee on 17/09/2012 and the amendments were approved.

Yours sincerely



Jane Carter
R&D Manager
on behalf of the R&D Committee

