Scotland A REC

Telephone:

11 December 2017

Prof Joanne Booth Professor of Rehabilitation Nursing Glasgow Caledonian University School of Health & Life Sciences Glasgow Caledonian University Cowcaddens Road, Glasgow G4 0BA

Dear Prof Booth

Study title:	ELECtric Tibial nerve stimulation to Reduce
	Incontinence in Care homes: ELECTRIC
REC reference:	17/SS/0117
Protocol number:	16-040
IRAS project ID:	224515

Thank you for your letter of 17 November 2017. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 08 November 2017

Documents received

The documents received were as follows:

Document	Version	Date
Response Letter to Scotland A REC		17 November 2017
Participant information sheet (PIS) [ELECTRIC_ResidentAphasiaOrIncapacityPIL]	2.0	17 November 2017
Participant information sheet (PIS) [ELECTRIC AWI Relatives/Proxy Information Leaflet]	2.0	17 November 2017
Research protocol or project proposal [ELECTRIC_V1.0_Protocol]	1.0	17 November 2017

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	Version	Date
Response Letter to Scotland A REC		17 November 2017
Covering letter on headed paper		08 August 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [ELECTRIC_GCU_ELPLinsurane]		15 July 2017
GP/consultant information sheets or letters [ELECTRIC Trial GP Letter]		11 July 2017
Interview schedules or topic guides for participants [ELECTRIC Topic Guide CH managers]		16 July 2017
Interview schedules or topic guides for participants [ELECTRIC Interview topic guide CH staff]		16 July 2017
Interview schedules or topic guides for participants [ELECTRIC Interview topic guide residents/family]	1.0	16 July 2017
Letter from funder [Booth agree to fund letter.pdf]	NA	28 March 2017
Letter from sponsor [Sponsorletter_ELETRIC 030817]	NA	03 August 2017
Letters of invitation to participant [ELECTRIC Letter of invitation to potential participants]		11 July 2017
Non-validated questionnaire [ELECTRIC FC-PBC]	1.0	07 August 2017
Non-validated questionnaire [ELECTRIC S-PBC]	1.0	07 August 2017
Non-validated questionnaire [ELECTRIC RUQ_070817]	1.0	07 August 2017
Non-validated questionnaire [ELECTRIC RUQ_070817 6week]	1.0	07 August 2017
Non-validated questionnaire [ELECTRIC RUQ_070817 18week]	1.0	07 August 2017
Participant consent form [ELECTRIC Resident Standard Consent Form]		11 July 2017
Participant consent form [ELECTRIC: Aphasia/incapacity Consent form]		11 July 2017
Participant consent form [ELECTRIC Relatives AWI Proxy Consent Form]		11 July 2017
Participant consent form [ELECTRIC Relative/Friend Consent Form		16 July 2017
Participant consent form [ELECTRIC Staff Consent Form]	1.0	16 July 2017
Participant information sheet (PIS) [ELECTRIC_Residents Standard PIL]		10 July 2017
Participant information sheet (PIS) [ELECTRIC Relatives Participant Information Leaflet]		16 August 2017
Participant information sheet (PIS) [ELECTRIC Staff Participant Information Leaflet]		16 July 2017
Participant information sheet (PIS) [ELECTRIC_ResidentAphasiaOrIncapacityPIL]		17 November 2017
Participant information sheet (PIS) [ELECTRIC AWI Relatives/Proxy Information Leaflet]		17 November 2017
REC Application Form [REC_Form_10082017]		10 August 2017
Research protocol or project proposal [ELECTRIC_V1.0_Protocol]	1.0	17 November 2017
Summary CV for Chief Investigator (CI)		14 July 2017
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flowcharts_ELECTRIC]	1.0	17 July 2017

Validated questionnaire [ELECTRIC PPBC]	1.0	07 August 2017
Validated questionnaire [Demqol-questionnaire_v4.pdf]	v4	09 August 2017
Validated questionnaire [demquol-proxy-questionnaire_v42011.pdf]	v4	09 August 2011
Validated questionnaire [ELECTRIC MTSQ]	1.0	07 August 2017

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

17/SS/0117	Please quote this number on all correspondence

Yours sincerely

REC Manager

E-mail:

Copy to: