

South East Scotland REC 02

2 - 4 Waterloo Place
Edinburgh
EH1 3EG

Telephone: 0131 465 5674
Fax:

18 December 2017

Dr Ho-Yan Yvonne Chun
Clinical research fellow
University of Edinburgh
Centre for Clinical Brain Sciences
Chancellor's Building, 49 Little France Crescent
Edinburgh
EH16 4SB

Dear Dr Chun

Study title: Treating Anxiety after Stroke (TASK) – feasibility
randomized controlled trial
REC reference: 17/SS/0143
Protocol number: AC17087
IRAS project ID: 228995

Thank you for your letter of 5th December 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 24 November 2017

Documents received

The documents received were as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		05 December 2017
GP/consultant information sheets or letters [GP letter]	3	01 December 2017
Non-validated questionnaire [participant feedback screenshots]		
Other [electronic PIS screenshots]		
Other [the TASK electronic ICF v3_1.12.17]		
Participant consent form [participant consent form (paper)]	3	01 December 2017
Participant information sheet (PIS) [paper PIS]	3	01 December 2017
Research protocol or project proposal [TASK Protocol]	3	01 December 2017
Response to Additional Conditions Met [Response to additional conditions met cover letter]		05 December 2017

Approved documents

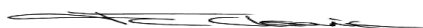
The final list of approved documentation for the study is therefore as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Copies of advertisement materials for research participants [Links to TASK websites]	1	10 October 2017
Costing template (commercial projects) [Funding source]		
Covering letter on headed paper		05 December 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Professional indemnity]		04 August 2017
GP/consultant information sheets or letters [GP letter]	3	01 December 2017
IRAS Application Form [IRAS_Form_16102017]		16 October 2017
Letters of invitation to participant [Letter from treating physician]	2	10 October 2017
Non-validated questionnaire [participant feedback screenshots]		
Other [public liability insurance University of Edinburgh]		
Other [electronic PIS screenshots]		
Other [the TASK electronic ICF v3_1.12.17]		
Participant consent form [participant consent form (paper)]	3	01 December 2017
Participant information sheet (PIS) [paper PIS]	3	01 December 2017
Research protocol or project proposal [TASK Protocol]	3	01 December 2017
Response to Additional Conditions Met [Response to additional conditions met cover letter]		05 December 2017
Summary CV for Chief Investigator (CI) [CV of CI]	1	14 September 2017
Summary of any applicable exclusions to sponsor insurance (non-NHS sponsors only) [clinical trial liability insurance]		27 July 2017
Validated questionnaire [questionnaire set including mRS, EQ5D5L-VAS, PHQ2, GAD7, and FQ]		18 October 2017
Validated questionnaire [Follow up surveys screenshots]		

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/0143	Please quote this number on all correspondence
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Yours sincerely



Joyce Clearie
SESREC 2 Manager

E-mail: joyce.clearie@nhslothian.scot.nhs.uk

Copy to: , NHS Lothian Research and Development Office