

Subject **IRAS ID 183040. Confirmation of Amendment Assessment**  
From amendments hra (HEALTH RESEARCH AUTHORITY) <hra.amendments@nhs.net>  
To Rupert Pearse <r.pearse@qmul.ac.uk>, Richard Haslop <r.haslop@qmul.ac.uk>  
Cc amendments hra (HEALTH RESEARCH AUTHORITY) <hra.amendments@nhs.net>, <sponsorsrep@bartshealth.nhs.uk>  
Date 14/06/2016 13:30



- 183040\_15 LO 1595 fav op sub amend 1 letter.pdf (~103 KB)

Dear Professor Pearse

## Confirmation of Amendment Assessment

**IRAS ID:** 183040 (*Please quote this on all correspondence*)  
**Amendment number:** Substantial Amendment 1  
**Amendment date:** 01 March 2016

Thank you for your submission to the HRA of the above referenced amendment to a study which was processed through pre-HRA Approval systems, details of which are in the attached REC letter.

The amendment has been assessed against HRA standards relating to the legal and regulatory aspects of the study and this email confirms that these standards have been met, including that any and all applicable regulatory approvals are in place.

The sponsor should now work collaboratively with participating NHS organisations in England to implement the amendment as per the categorisation email, including (where applicable), providing a copy of this email to confirm that the amendment fulfils the relevant standards.

Please note that this was not a full assessment of the study against all HRA Approval standards but a review of the amendment only. As such, this email **does not** confer HRA Approval to the study.

### User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please email the HRA at [hra.approval@nhs.net](mailto:hra.approval@nhs.net). Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

### HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>.

Yours sincerely

Gemma Oakes  
HRA Assessor



**Health Research Authority**  
HRA, Ground Floor, Skipton House, 80 London Road, London, SE1 6LH  
E: [hra.amendments@nhs.net](mailto:hra.amendments@nhs.net)  
[www.hra.nhs.uk](http://www.hra.nhs.uk)

The HRA is keen to know your views on the service you received – our short feedback form is available [here](#)

\*\*\*\*\*  
This message may contain confidential information. If you are not the intended recipient please inform the sender that you have received the message in error before deleting it.  
Please do not disclose, copy or distribute information in this e-mail or take any action in reliance on its contents:  
to do so is strictly prohibited and may be unlawful.

Thank you for your co-operation.

NHSmial is the secure email and directory service available for all NHS staff in England and Scotland  
NHSmial is approved for exchanging patient data and other sensitive information with NHSmial and GSi recipients  
NHSmial provides an email address for your career in the NHS and can be accessed anywhere

\*\*\*\*\*