

Hannah Swayze

From: berkshire.rec@hra.nhs.uk <noreply@harp.org.uk>
Sent: 14 April 2020 16:16
To: Christopher Butler; CTRG Sponsorship Correspondence
Cc: Hannah Swayze
Subject: IRAS PROJECT ID 281958, REC Reference 20/SC/0158 Confirmation of favourable opinion for substantial amendment
Attachments: IRAS 281958 SL32_Favourable_opinion_of_a_substantial_amendment-9.pdf

Dear Dr Butler

IRAS project ID:	281958
REC reference:	20/SC/0158
Short Study title:	PRINCIPLE
Date complete amendment submission received:	09 April 2020
Amendment No./ Sponsor Ref:	SA2
Amendment Date:	07 April 2020
Amendment Type:	Substantial
Outcome of HRA Assessment	This email also constitutes HRA and HCRW Approval for the amendment, and you should not expect anything further.

I am pleased to confirm that this amendment has been reviewed by the Research Ethics Committee and has received a Favourable Opinion. Please find attached a copy of the Favourable Opinion letter.

HRA and HCRW Approval Status

As detailed above, **this email also constitutes HRA and HCRW Approval for the amendment**. No separate notice of HRA and HCRW Approval will be issued. You should implement this amendment at NHS organisations in England and/or Wales, in line with the conditions outlined in your categorisation email.

- If this study has HRA and HCRW Approval, this amendment may be implemented at participating NHS organisations in England and/or Wales once the conditions detailed in the categorisation section above have been met
- If this study is a pre-HRA Approval study, this amendment may be implemented at participating NHS organisations in England and/or Wales that have NHS Permission, once the conditions detailed in the categorisation section above have been met. For participating NHS organisations in England and/or Wales that do not have NHS Permission, these sites should be covered by HRA and HCRW Approval before the amendment is implemented at them, please see below;
- If this study is awaiting HRA and HCRW Approval, I have passed your amendment to my colleague and you should receive separate notification that the study has received HRA and HCRW Approval, incorporating approval for this amendment.

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 use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>.

If you require further information, please contact amendments@hra.nhs.uk

20/SC/0158/AM02 Please quote this number on all correspondence

Kind regards

Alison Doherty

Approvals Administrator

Health Research Authority

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