

Hannah Swayze

From: berkshire.rec@hra.nhs.uk <noreply@harp.org.uk>
Sent: 20 May 2020 12:16
To: Christopher Butler; CTRG Sponsorship Correspondence
Cc: nhsg.nrspcc@nhs.net; Hannah Swayze
Subject: IRAS 281958. Amendment confirmation of REC Validation, categorisation and implementation information
Attachments: IRAS 281958 SL27
_Acknowledgement_of_a_valid_notice_of_a_substantial_amendment-1.pdf
Follow Up Flag: Flag for follow up
Flag Status: Flagged

Amendment Confirmation of REC Validation, Categorisation and Implementation Information

Dear Professor Butler,

IRAS Project ID:	281958
Short Study Title:	PRINCIPLE
Date complete amendment submission received:	20 May 2020
Amendment No./ Sponsor Ref:	SA5
Amendment Date:	20 May 2020
Amendment Type:	Substantial
Outcome of HRA and HCRW Assessment	HRA and HCRW Approval for the amendment is pending. HRA and HCRW Approval for the amendment will be separately confirmed by email.
Implementation date in NHS organisations in England and/or Wales	2 days from date amendment information together with this email, is supplied to participating organisations (provided HRA and HCRW Approval for the amendment is in place and conditions are met)
Implementation date in NHS/HSC organisations in Northern Ireland and/or Scotland	24th June 2020 (providing conditions are met)
For NHS/HSC R&D Office information	
Amendment Category	A

Thank you for submitting an amendment to your project. We have now categorised your amendment and please find this, as well as other relevant information, in the table above.

Please also find attached a copy of the REC validation letter for the submitted amendment.

What should I do next?

Please read the information in [IRAS](#), which provides you with information on how and when you can implement your amendment at NHS/HSC sites in each nation, and what actions you should take now.

If you have participating NHS/HSC organisations in any other UK nations that are affected by this amendment please note that **we will** forward the amendment submission to the relevant national coordinating function(s).

If not already provided, please email to us any regulatory approvals (where applicable) once available. Your amendment will be reviewed by the REC, as per the attached letter.

When can I implement this amendment?

You may implement this amendment in line with the information in [IRAS](#). Please note that you may only implement changes described in the amendment notice.

Information relating to the addition of new sites.

This amendment also adds new participating NHS/HSC organisations to the study. The 35 day implementation date does not apply to the new sites. Please set up new sites as detailed below (as processes change from time to time, we recommend that you refer to the most up to date guidance about site set up, found within [IRAS](#)).

If your study is supported by a research network, please contact the network as early as possible to help support set up of the new site(s).

For new sites in Northern Ireland and/or Scotland:	Please start to set up your new sites. Sites may not open until a REC Favourable Opinion and NHS/HSC management permission is in place.
For new sites in England and/or Wales:	For studies which already have HRA and HCRW Approval: HRA and HCRW Approval for the amendment is pending. You can start the process of setting up the new site but cannot open the study at the site until HRA and HCRW Approval for the amendment is in place and the site has confirmed capacity and capability (where applicable). For studies which do not yet have HRA and HCRW Approval: HRA and HCRW Approval for the <u>initial application</u> is pending and you will receive this in due course. You can start the process of setting up the new site but cannot open the study at the site until HRA and HCRW Approval is in place and the site has confirmed capacity and capability (where applicable).

Who should I contact if I have further questions about this amendment?

If you have any questions about the ethical review of this amendment, please do not hesitate to contact me.

If you have any other questions about this amendment please contact the relevant national coordinating centre for advice:

- England – amendments@hra.nhs.uk
- Northern Ireland – research.gateway@hscni.net
- Scotland – nhsq.NRSPCC@nhs.net
- Wales – HCRW.amendments@wales.nhs.uk

Additional information on the management of amendments can be found in the [IRAS guidance](#).

Please do not hesitate to contact me if you require further information.

Kind regards

Alison Doherty
Approvals Administrator
Health Research Authority

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E. amendments@hra.nhs.uk

W. www.hra.nhs.uk

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