

Pakats, Mari-Liis

From: hra.amendments@nhs.net <noreply@harp.org.uk>
Sent: 20 November 2018 15:35
To: r.pearse@qmul.ac.uk; admin@prismtrial.org
Cc: nhsg.nrspcc@nhs.net; research-permissions@wales.nhs.uk; spnsorsrep@bartshealth.nhs.uk
Subject: IRAS 183040. Amendment categorisation and implementation information
Attachments: 15_LO_1595_AM14_ChecklistDownload-2018-11-20-15_33_00.zip

Amendment Categorisation and Implementation Information

Dear Professor Pearse,

IRAS Project ID:	183040
Short Study Title:	PRISM
Date complete amendment submission received:	19 November 2018
Amendment No./ Sponsor Ref:	Minor Amendment 12
Amendment Date:	08 November 2018
Amendment Type:	Non-substantial
Outcome of HRA and HCRW Assessment	This email also constitutes HRA and HCRW Approval for the amendment, and you should not expect anything further.
Implementation date in NHS organisations in England and Wales	35 days from date amendment information together with this email, is supplied to participating organisations (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.

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 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.

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.

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

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

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

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

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/>.

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

Kind regards

Mrs Kirsten Peck
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