

Wilson A.K.

From: hra.amendments@nhs.net <noreply@harp.org.uk>
Sent: 04 April 2018 12:10
To: Foster C.L.; Horizons
Cc: sharon.davies-dear@uhs.nhs.uk; syeda.khatun3@nhs.net
Subject: IRAS 202342. Amendment categorisation and implementation information

Categories: Amber

Amendment Categorisation and Implementation Information

Dear Professor Foster,

IRAS Project ID:	202342
Short Study Title:	HORIZONS: Understanding the impact of cancer diagnosis and treatment
Date complete amendment submission received:	20 March 2018
Amendment No./ Sponsor Ref:	9
Amendment Date:	12 March 2018
Amendment Type:	Non-substantial
Outcome of HRA Assessment	This email also constitutes HRA Approval for the amendment , and you should not expect anything further from the HRA.
Implementation date in NHS organisations in England	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	B

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.

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, Scotland and/or Wales only:	Please start to set up your new sites. Sites may not open until NHS/HSC management permission is in place.
For new sites in England only:	<p><u>For studies which already have HRA Approval:</u> This email also constitutes HRA Approval for the amendment, and you should not expect anything further from the HRA. Please start to set up your new sites. Sites may not open until the site has confirmed capacity and capability (where applicable).</p> <p><u>For studies which do not yet have HRA Approval:</u> HRA Approval for the <u>initial application</u> is pending and you will receive confirmation of HRA Approval. You can start the process of setting up the new site but cannot open the study at the site until HRA Approval is in place and the site has confirmed capacity and capability (where applicable).</p>

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 – nhsg.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

Sarah Urmson

Health Research Authority

Ground Floor | Skipton House | 80 London Road | London | SE1 6LH

E.hra.amendments@nhs.net

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