

Wilson A.K.

From: AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY)
<hra.amendments@nhs.net>
Sent: 15 February 2018 09:04
To: Cole A.B.
Cc: Foster C.L.; Horizons; sharon.davies-dear@uhs.nhs.uk; NRSPCC, Nhsg (NHS GRAMPIAN); 'research.amendments@hscni.net'
Subject: IRAS 202342 Amendment Categorisation and Implementation Information
Attachments: image002.emz; 16_NW_0425_AM15_ChecklistDownload-2018-02-15-08_58_49.zip

Amendment Categorisation and Implementation Information

Dear Amber

Thank you for submitting an amendment to your project.

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

Please note that you may only implement changes described in the amendment notice.

What Happens Next?

Information Specific to Participating NHS Organisations in England

1. You should now share details of the amendment and, if applicable, your amended documents, together with this email, with participating NHS organisations in England that are affected by this amendment. In doing so, you should include the [NHS R&D Office](#), [LCRN](#) (where applicable) as well as the local research team. A template email to notify participating NHS organisations in England is provided on the [HRA website](#).
2. You do not need to share with participating NHS organisations in England that are not affected by this amendment.
3. The participating NHS organisations in England that are affected by this amendment should prepare to implement.
4. Your amendment has been assessed against [HRA standards](#). **This email also constitutes HRA Approval for the amendment, and you should not expect anything further from the HRA.**
5. You may implement your amendment at affected participating NHS organisations in England 35 calendar days from the day on which you provide the organisations with this email and your amended documents (or as soon as the participating NHS organisation confirm that you may implement, if sooner). **NHS organisations do not have to confirm they are happy with the amendment.**
6. You may not implement the amendment at any participating NHS organisations in England that requests additional time to assess, until it confirms that it has concluded its assessment.
7. You may not implement at any participating NHS organisation in England that declines to implement the amendment.

Information Specific to Participating NHS/HSC Organisations in Northern Ireland, Scotland and/or Wales

1. You should now share details of the amendment and, if applicable, your amended documents, together with this email, with the research teams at participating NHS/HSC organisations in Northern Ireland, Scotland and/or Wales that are affected by this amendment.
2. You do not need to include the R&D offices in this correspondence, as we have separately made it available via their national coordinating functions.
3. You do not need to share with participating NHS/HSC organisations in Northern Ireland, Scotland and/or Wales that are not affected by this amendment.
4. The participating NHS/HSC organisations that are affected by this amendment should prepare to implement.
5. You may implement your amendment at affected NHS/HSC participating organisations in Northern Ireland, Scotland and/or Wales on the date provided in the table below (or as soon as the participating NHS/HSC organisation confirm that you may implement, if sooner). **NHS/HSC organisations do not have to confirm they are happy with the amendment.** If you receive any applicable regulatory approval subsequent to this date, you may implement once you receive the last relevant approval. Please note that HRA Approval is not required to implement this amendment outside of England.
6. You may not implement the amendments at any participating NHS/HSC organisation that requests additional time to assess, until it confirms that it has concluded its assessment.
7. You may not implement at any participating NHS/HSC organisation that declines to implement the amendment.

IRAS Project ID:	202342
Short Study Title:	HORIZONS: Understanding the impact of cancer diagnosis and treatment
Date complete amendment submission received:	6 February 2018
Sponsor Amendment Reference Number:	Non substantial Amendment 8
Sponsor Amendment Date:	29 January 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
Implementation date in NHS/HSC organisations in Northern Ireland, Scotland and/or Wales	13 March 2018 (providing conditions above are met)
For NHS/HSC R&D Office information	
Amendment Category	B

Information relating to the addition of new sites

This amendment also adds new participating NHS/HSC organisations to the study.

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).

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](#)).

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:	<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). <u>For studies which do not yet have HRA Approval:</u> HRA Approval 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).

If you have any questions relating to the wider HRA approval process, please direct these to hra.approval@nhs.net

If you have any questions relating this amendment in one of the devolved administrations, please direct these to the relevant [national coordinating function](#).

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

Kirsten



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IMPORTANT – [Click here](#) for the latest details of the roll-out of HRA Approval in England

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

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