

On 12 Apr 2018, at 11:43, IP GROOT BLUEMINK, Marjolein (HEALTH RESEARCH AUTHORITY) <> wrote:

Dear Dr Savic

Further to the below, I am pleased to confirm **HRA Approval** for the referenced amendment.

You should implement this amendment at NHS organisations in England, in line with the conditions outlined in your categorisation email.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Kind regards

Maeve

Maeve Ip Groot Bluemink
Assessor
Health Research Authority
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From: hra.amendments@nhs.net [<mailto:hra.amendments@nhs.net>]

Sent: 10 April 2018 17:08

Subject: IRAS 232512. Amendment categorisation and implementation information

Amendment Categorisation and Implementation Information

Dear Dr Savic

IRAS Project ID:	232512
REC Reference:	17/LO/2106
Short Study Title:	Drug Allergy Labels in the Elective Surgical Population
Date complete amendment submission received:	26 March 2018

Sponsor Amendment Reference Number:	Non Substantial Amendment - 26 March 2018
Sponsor Amendment Date:	26 March 2018
Amendment Type	Non Substantial
Outcome of HRA Assessment	HRA Approval for the amendment is pending. The HRA will separately confirm HRA Approval for the amendment by email.
For NHS/HSC R&D Office information	
Amendment Category	C

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?

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).

You should now inform participating NHS/HSC organisations of the amendment.

- ? For NHS/HSC organisations in the Devolved Administrations this notification should be to the research team at participating NHS/HSC organisations. You do not need to inform the R&D offices, as we have separately made it available via their national coordinating functions.
- ? For NHS organisations in England, this notification should include the [NHS R&D Office](#), [LCRN](#) (where applicable) as well as the local research team.

When can I implement this amendment?

You may implement this amendment as soon as any relevant regulatory approvals are in place. For participating NHS organisations in England this includes receiving HRA Approval for the amendment – you should receive a separate notification confirming this, and is applicable for participating English NHS organisations only.

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 – nhsg.NRSPCC@nhs.net

Wales – research-permissions@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

Mrs Kirsten Peck

HRA Approval Amendment Coordinator

Health Research Authority

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E. hra.amendments@nhs.net

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