

Richard Haynes

From: CambridgeEast.REC@hra.nhs.uk <noreply@harp.org.uk>
Sent: 14 October 2020 13:33
To: peter.horby@ndm.ox.ac.uk; ctrg@admin.ox.ac.uk; Richard Haynes
Cc: nhsg.nrspcc@nhs.net; research.amendments@hscni.net;
HCRW.amendments@wales.nhs.uk
Subject: 20/EE/0101/AM11 IRAS 281712. Amendment confirmation of REC validation, categorisation and implementation information
Attachments: 20EE0101AM11 , IRAS Project ID 281712 SL27
_Acknowledgement_of_a_valid_notice_of_a_substantial_amendment.pdf

Amendment Confirmation of REC Validation, Categorisation and Implementation Information

Dear Horby,

IRAS Project ID:	281712
Short Study Title:	RECOVERY trial [COVID-19] [UPH]
Date complete amendment submission received:	13 October 2020
Amendment No./ Sponsor Ref:	Substantial Amendment 9
Amendment Date:	11 October 2020
Amendment Type:	Substantial
Outcome of HRA and HCRW Assessment	HRA and HCRW Approval for the amendment is pending – other regulatory approvals. HRA and HCRW Approval for the amendment will be separately confirmed 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.

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

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 Northern Ireland and/or Scotland 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 and/or Wales, 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 and/or Wales this includes receiving HRA and HCRW Approval for the amendment – you should receive a separate notification confirming this, and is applicable for participating English and Welsh 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 – 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

Joy Uzoma

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E. amendments@hra.nhs.uk

W. www.hra.nhs.uk

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