

Richard Haynes

From: CambridgeEast.REC@hra.nhs.uk <noreply@harp.org.uk>
Sent: 15 May 2020 14:41
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/AM07 IRAS 281712. Amendment confirmation of REC Validation, categorisation and implementation information
Attachments: 20EE0101AM07 , IRAS Project ID 281712 SL27
_Acknowledgement_of_a_valid_notice_of_a_substantial_amendment-2.pdf

Amendment Confirmation of REC Validation, Categorisation and Implementation Information

Dear Horby,

IRAS Project ID:	281712
Short Study Title:	RECOVERY Trial
Date complete amendment submission received:	15 May 2020
Amendment No./ Sponsor Ref:	SA5
Amendment Date:	14 May 2020
Amendment Type:	Substantial
Outcome of HRA and HCRW Assessment	HRA and HCRW Approval for the amendment is pending – other regulatory approvals. HRA an HCRW Approval for the amendment will be separately confirmed by email.
Implementation date in NHS organisations in England and/or Wales	03 days from date of HRA and HCRW approval
Implementation date in NHS/HSC organisations in Northern Ireland and/or Scotland	03 days from date of HRA and HCRW approval
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.

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

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 that are affected by this amendment 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. Your amendment will be reviewed by the REC, as per the attached letter.

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 the ethical review of this amendment, please do not hesitate to contact me.

If you have any other 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

Health Research Authority

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E. amendments@hra.nhs.uk

W. www.hra.nhs.uk

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