Richard Haynes

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Sent: 23 June 2020 16:06

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/AM08 IRAS 281712. Amendment categorisation and implementation

information

Attachments: 20EE0101AM08 , IRAS Project ID 281712 SL27

_Acknowledgement_of_a_valid_notice_of_a_substantial_amendment.pdf

Amendment Categorisation and Implementation Information

Dear Horby

IRAS Project ID:	281712	
REC Reference:	20/EE/0101	
Short Study Title:	RECOVERY Trial [COVID-19] [UPH]	
Date complete amendment submission received:	23 June 2020	
Sponsor Amendment Reference Number:	Substantial Amendment 6	
Sponsor Amendment Date:	23 June 2020	
Amendment Type	Substantial	
Outcome of HRA and HCRW Assessment	HRA and HCRW Approval for the amendment is pending - HRA and HCRW Approval for the amendment will be separately confirmed by email.	
Implementation date in NHS organisations in England and Wales	03 days from date of HCRW Approval	
Implementation date in NHS/HSC organisations in Northern Ireland, and/or Scotland	03 Days from date of 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.

What should I do next?

Please read the information in <u>IRAS</u>, which provides you with information on how and when you can implement your amendment at NHS/HSC sites in each nation, and <u>what actions you should take now</u>.

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 <u>IRAS</u>. 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 nhsg.NRSPCC@nhs.net
- Wales HCRW.amendments@wales.nhs.uk

Additional information on the management of amendments can be found in the <u>IRAS guidance</u>.

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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