

Richard Haynes

From: Cambridge East <cambridgeeast.rec@hra.nhs.uk>
Sent: 16 December 2020 10:40
To: Richard Haynes; 'peter.horby@ndm.ox.ac.uk'
Cc: 'nhsg.nrspcc@nhs.net'; 'research.gateway@hscni.net'; 'Researchgw Amendments'; Catherine Adams
Subject: 20/EE/0101/AM15 IRAS 281712. Amendment categorisation and implementation information

Amendment Categorisation and Implementation Information

Dear Professor Horby

IRAS Project ID:	281712
REC Reference:	20/EE/0101
Short Study Title:	RECOVERY trial [COVID-19] [UPH]
Date complete amendment submission received:	15 December 2020
Sponsor Amendment Reference Number:	Substantial Amendment 12
Sponsor Amendment Date:	15 December 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	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?

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 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 [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 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

Ground Floor | Skipton House | 80 London Road | London | SE1 6LH

E. amendments@hra.nhs.uk

W. www.hra.nhs.uk

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