

Richard Haynes

From: CambridgeEast.REC@hra.nhs.uk <noreply@harp.org.uk>
Sent: 18 March 2020 14:40
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; Jill Barton; barbarafarrell1@hotmail.com;
Agnieszka.Ziolek@hra.nhs.uk; Catherine.Adams@hra.nhs.uk
Subject: IRAS 281712. Amendment categorisation and implementation information

Amendment Categorisation and Implementation Information

Dear Horby

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|---|---|
| IRAS Project ID: | 281712 |
| REC Reference: | 20/EE/0101 |
| Short Study Title: | RECOVERY trial |
| Date complete amendment submission received: | 18 March 2020 |
| Sponsor Amendment Reference Number: | Non Substantial Amendment 1 |
| Sponsor Amendment Date: | 17 March 2020 |
| Amendment Type: | Non-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: | 35 days from date amendment information together with this email, is supplied to participating organisations (provided HRA and HCRW Approval is in place and conditions are met) |
| 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 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

Miss Saira Adil

Health Research Authority

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

E. amendments@hra.nhs.uk

W. www.hra.nhs.uk