

Jenner, Richard

From: londonsoutheast.rec@hra.nhs.uk <noreply@harp.org.uk>
Sent: 18 June 2020 10:01
To: Graham.Collins; CTC.Animate
Cc: nhsg.nrspcc@nhs.net; HCRW.amendments@wales.nhs.uk
Subject: IRAS 216147. Amendment categorisation and implementation information
Attachments: 216147 18.LO.0204 SA6 Validation Letter.pdf

Amendment Categorisation and Implementation Information

Dear Dr Collins

IRAS Project ID:	216147
REC Reference:	18/LO/0204
Short Study Title:	ANIMATE
Date complete amendment submission received:	17 June 2020
Sponsor Amendment Reference Number:	Substantial Amendment 6
Sponsor Amendment Date:	28 May 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	35 days from date amendment information together with this email, is supplied to participating organisations (provided HRA and HCRW Approval for the amendment is in place and conditions are met)
Implementation date in NHS/HSC organisations in Northern Ireland, and/or Scotland	23 July 2020 (providing conditions are met)
For NHS/HSC R&D Office information	

Amendment Category	A
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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 – nhsg.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

Faye Slade

Approvals Administrator

Health Research Authority

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

[E. amendments@hra.nhs.uk](mailto:E.amendments@hra.nhs.uk)

[W. www.hra.nhs.uk](http://www.hra.nhs.uk)

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