

**Patrick, Pip**

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**From:** MASHEGEDE, Beverley (HEALTH RESEARCH AUTHORITY)  
<beverleymashegede@nhs.net>  
**Sent:** 08 May 2018 12:42  
**To:** graham.collins@ouh.nhs.uk; CTC.Animate  
**Cc:** ouhtma@ouh.nhs.uk; Schofield, Oliver  
**Subject:** RE: IRAS 216147. HRA Approval for the Amendment

Dear Dr Collin,  
Further to the below, I am pleased to confirm **HRA Approval** for the referenced amendment.

You should implement this amendment at NHS organisations in England, in line with the conditions outlined in your categorisation email.

Please contact [hra.amendments@nhs.net](mailto:hra.amendments@nhs.net) for any queries relating to the assessment of this amendment.

Kind Regards

Beverley

**Beverley Mashegede**  
**Assessor**  
**Health Research Authority**  
The Old Chapel | Royal Standard Place | Nottingham | NG1 6FS  
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**E.** [beverleymashegede@nhs.net](mailto:beverleymashegede@nhs.net)  
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**From:** nrescommittee.london-southeast@nhs.net [mailto:nrescommittee.london-southeast@nhs.net]  
**Sent:** 17 April 2018 14:54  
**To:** graham.collins@ouh.nhs.uk; ctc.animate@ucl.ac.uk  
**Cc:** nhsg.nrspcc@nhs.net; research-permissions@wales.nhs.uk; ouhtma@ouh.nhs.uk  
**Subject:** IRAS 216147. Amendment confirmation of REC Validation, categorisation and implementation information

### Amendment Confirmation of REC Validation, Categorisation and Implementation Information

Dear Dr Collins,

<b>IRAS Project ID:</b>	216147
<b>Short Study Title:</b>	ANIMATE
<b>Date complete amendment submission received:</b>	13 April 2018

<b>Amendment No./ Sponsor Ref:</b>	Substantial Amendment 2
<b>Amendment Date:</b>	13 April 2018
<b>Amendment Type:</b>	Substantial
<b>Outcome of HRA Assessment</b>	<b>HRA Approval for the amendment is pending.</b> The HRA will separately confirm HRA Approval for the amendment by email.
<b>Implementation date in NHS organisations in England</b>	35 days from date amendment information together with this email, is supplied to participating organisations ( <b>provided HRA Approval for the amendment is in place and conditions are met</b> )
<b>Implementation date in NHS/HSC organisations in Northern Ireland, Scotland and/or Wales</b>	18th May 2018 ( <b>providing conditions are met</b> )
For NHS/HSC R&D Office information	
<b>Amendment Category</b>	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.

### Information relating to the addition of new sites.

This amendment also adds new participating NHS/HSC organisations to the study. The 35 day implementation date does not apply to the new sites. Please set up new sites as detailed below (as processes change from time to time, we recommend that you refer to the most up to date guidance about site set up, found within [IRAS](#)).

If your study is supported by a research network, please contact the network as early as possible to help support set up of the new site(s).

<b>For new sites in England only:</b>	For studies which already have HRA Approval: <b>HRA Approval for the amendment is pending.</b> You can start the process of setting up the new site but cannot open the study at the site until HRA Approval for the amendment is in place and the site has confirmed capacity and capability (where applicable).
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**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 – [hra.amendments@nhs.net](mailto:hra.amendments@nhs.net)
- Northern Ireland – [research.gateway@hscni.net](mailto:research.gateway@hscni.net)
- Scotland – [nhsg.NRSPCC@nhs.net](mailto:nhsg.NRSPCC@nhs.net)
- Wales – [research-permissions@wales.nhs.uk](mailto:research-permissions@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

**Julie Acourt**

**REC Assistant**

**Health Research Authority**

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

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

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

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## Schofield, Oliver

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**From:** nrescommittee.london-southeast@nhs.net <noreply@harp.org.uk>  
**Sent:** 17 April 2018 14:54  
**To:** graham.collins@ouh.nhs.uk; CTC.Animate  
**Cc:** nhsg.nrspcc@nhs.net; research-permissions@wales.nhs.uk; ouhtma@ouh.nhs.uk  
**Subject:** IRAS 216147. Amendment confirmation of REC Validation, categorisation and implementation information  
**Attachments:** 18 LO 0204 Ack valid SA2 17Apr18.pdf

### Amendment Confirmation of REC Validation, Categorisation and Implementation Information

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<b>Short Study Title:</b>	ANIMATE
<b>Date complete amendment submission received:</b>	13 April 2018
<b>Amendment No./ Sponsor Ref:</b>	Substantial Amendment 2
<b>Amendment Date:</b>	13 April 2018
<b>Amendment Type:</b>	Substantial
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- Scotland – [nhsq.NRSPCC@nhs.net](mailto:nhsq.NRSPCC@nhs.net)
- Wales – [research-permissions@wales.nhs.uk](mailto:research-permissions@wales.nhs.uk)

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**Julie Acourt**

**REC Assistant**

**Health Research Authority**

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