

## Anthony Marshall

**From:** nrescommittee.northwest-haydock@nhs.net <noreply@harp.org.uk>  
**Sent:** 02 October 2018 12:32  
**To:** Kimme Hyrich; MHS Ethics Applications; Anthony Marshall  
**Subject:** IRAS 64202.00/8/053 Amendment confirmation of REC Validation, categorisation and implementation information 02/10/2018  
**Attachments:** 64202 00.8.053 Valid NoSA 02.10.2018.pdf

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

Dear Dr Hyrich,

<b>IRAS Project ID:</b>	64202
<b>Short Study Title:</b>	Prospective observational study of the long-term hazards of anti-TNF therapy in rheumatoid arthritis
<b>Date complete amendment submission received:</b>	01 October 2018
<b>Amendment No./ Sponsor Ref:</b>	26
<b>Amendment Date:</b>	19 September 2018
<b>Amendment Type:</b>	Substantial
<b>Outcome of HRA and HCRW Assessment</b>	<b>HRA and HCRW Approval for the amendment is pending – other regulatory approvals.</b> HRA and HCRW Approval for the amendment will be separately confirmed by email.
<b>Implementation date in NHS organisations in England and/or Wales</b>	35 days from date amendment information together with this email, is supplied to participating organisations <b>(provided HRA and HCRW Approval for the amendment is in place and conditions are met)</b>
<b>Implementation date in NHS/HSC organisations in Northern Ireland and/or Scotland</b>	<b>05/11/2018 (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.

### **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

**Laila Sarwar**

**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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