

## Anthony Marshall

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**From:** AMENDMENTS, Hra (HEALTH RESEARCH AUTHORITY) <hra.amendments@nhs.net>  
**Sent:** 24 August 2017 14:03  
**To:** Anthony Marshall  
**Cc:** Kimme Hyrich; MHS Ethics Applications  
**Subject:** RE: 64202 00/8/053/AM30 SubAm25 Favourable opinion letter 24.08.2017

Dear Anthony,

Further to the below, I am pleased to confirm that HRA Approval has been issued for the referenced amendment, following assessment against the HRA criteria and standards.

The sponsor should now work collaboratively with participating NHS organisations in England to implement the amendment as per the below categorisation information. This email may be provided by the sponsor to participating organisations in England to evidence that the amendment has HRA Approval.

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

Kind regards

Ali Hussain  
Amendments Co-ordinator



**Health Research Authority**

HRA, Ground Floor, Skipton House, 80 London Road, London, SE1 6LH  
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[www.hra.nhs.uk](http://www.hra.nhs.uk)

The HRA is keen to know your views on the service you received – our short feedback form is available [here](#)

**From:** HAYDOCK, NRESCommittee.NorthWest- (HEALTH RESEARCH AUTHORITY)  
**Sent:** 24 August 2017 11:38  
**To:** Anthony Marshall <[Anthony.Marshall@manchester.ac.uk](mailto:Anthony.Marshall@manchester.ac.uk)> ([Anthony.Marshall@manchester.ac.uk](mailto:Anthony.Marshall@manchester.ac.uk))  
**Cc:** 'Kimme.Hyrich@manchester.ac.uk'; 'fbmhethics@manchester.ac.uk'  
**Subject:** 64202 00/8/053 SubAm25 Favourable opinion letter 24.08.2017

Dear Anthony,

<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>	03 August 2017
<b>Amendment No./ Sponsor Ref:</b>	25
<b>Amendment Date:</b>	17 July 2017
<b>Amendment Type:</b>	Substantial

I am pleased to confirm that this amendment has been reviewed by the REC and has received a Favourable Opinion. Please find attached a copy of the Favourable Opinion letter.

**Participating NHS Organisations in England – Confirmation of Assessment Arrangements**

Further to the details above, I can confirm that this amendment will be assessed by the HRA to confirm that it meets the expected criteria and standards. An Assessor from the HRA will contact you, and you will receive separate notification that the HRA Assessment is complete. You should not implement this amendment at participating NHS organisations in England until the outcome of the HRA assessment is confirmed, and the conditions detailed in the categorisation section above have been met.

If you require further information, please contact [hra.amendments@nhs.net](mailto:hra.amendments@nhs.net)

Best wishes,  
Laila

**Laila Sarwar**  
**REC Assistant**  
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