

Anthony Marshall

Subject: FW: SA26_IRAS 64202_REC 00/8/53_sponsor approval

From: MHS Ethics Applications
Sent: 20 September 2018 11:44
To: Anthony Marshall
Subject: SA26_IRAS 64202_REC 00/8/53_sponsor approval

Dear Anthony

Study Title: Prospective observational study of the long term hazards of anti-TNF therapy in rheumatoid arthritis.
REC Ref: 00/8/53
IRAS ID: 64202
Amendment Number and Date: SA26, 19/09/2018

Many thanks for sending notification of the proposed amendment to this study. I have reviewed the Notice of Substantial Amendment (NoSA) and associated documents and can confirm that there are no issues with what is being proposed. As such, I am able to confirm sponsor support for this amendment.

Please send a request for electronic authorisation in IRAS using the email address: Stacey.Body@manchester.ac.uk.

General Reminder for Substantial Amendments:

1. Once the Notice of Substantial Amendment (NoSA) form has been fully authorised in IRAS, you need to generate the final version of the form. Open up the amendment form, go to the 'submission' tab and then select 'proceed to submission'. **This does not submit your amendment** but it does generate the final version of the form. Depending on your settings, the form will automatically download or you can 'Print as PDF' from the 'submission history' table at the foot of the page. To submit the amendment, email the final NoSA PDF and any revised documents to the REC that originally approved the study; REC contact details are on your approval letter or can be found using the REC directory: <http://www.hra.nhs.uk/news/rec/>.
2. All amendments should be submitted as per the UK process for management of amendments. A summary flowchart is attached and further information about the submission process can be found at: <https://www.myresearchproject.org.uk/help/hlpamendments.aspx>
3. Once the amendment has been approved by the REC/HRA can you please send a copy of the Notice of Substantial Amendment (NoSA) form, any amended documents (if changes are requested by the REC/HRA) and the approval letter(s) to FBMHethics@manchester.ac.uk – these can be sent electronically. This is so that the study file can be updated.
4. Once the REC opinion and HRA outcome has been received please ensure that you send details of the amendment to the participating sites (R&D office **and** local research team) as per the REC/HRA email instructions. Any site approvals of the amendment should be sent to FBMHethics@manchester.ac.uk

Best wishes
Afzal

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