

Anthony Marshall

From: MHS Ethics Applications
Sent: 01 August 2017 13:14
To: Anthony Marshall
Subject: SA 25_REC: 00/8/53_Sponsor Approval
Attachments: hraapproval-amendments.pdf

Dear Andrew

Study Title: Prospective observational study of the long term hazards of anti-TNF therapy in rheumatoid arthritis
REC Ref: 00/8/53
Amendment Number and Date: SA 25 17.07.2017

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: lynne.macrae@manchester.ac.uk.

General Reminder for Substantial Amendments:

1. All amendments should be submitted as per the 'hraapproval-amendments' - see leaflet attached. For further information on the process in England please see:
<http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/amendments-nhs-england-studies/>.
2. Once the amendment has been approved by the REC/HRA can you please send a copy of the notice of substantial amendment form, any amended documents (if changes are requested by the REC/HRA) and the approval letter(s) to fbmhethics@manchester.ac.uk - these can all be sent electronically. This is so that the study file can be updated and so the documents are submitted for information only.
3. All substantial amendment must be confirmed by the relevant NHS Trust management organisation prior to implementation at each site. Once the REC opinion and HRA outcome has been received, please send details of the amendment to the participating sites (R&D office and local research team), the sites will provide confirmation the amendment can be implemented. Please send a copy of Trust approval for the amendment to fbmhethics@manchester.ac.uk.

Many thanks
Afzal

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