

Anthony Marshall

From: MHS Ethics Applications
Sent: 07 April 2021 12:23
To: Anthony Marshall
Subject: SA28, IRAS 64202, REC 00/8/53, sponsor approval
Attachments: sponsor_approved_BSRBR-RA (IRAS 64202)_SA28_29032021.xlsm

Dear Anthony,

Study Title: Toxicity from biologic therapy (BSRBR-RA)

REC Ref: 00/8/53

IRAS ID: 64202

Amendment Number and Date: SA28, 29/03/2021

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

Please find your attached Amendment Tool which has now been authorised by us on behalf of the sponsor.

Face-to-face/direct physical contact with participants (standard guidance): This guidance is being issued for all amendments but only applies to face-to-face activities with research participants. If data collection/ research activities do not involve direct contact with participants, please continue to the submission guidance below.

Whilst COVID-19 restrictions remain in place, there may be additional assurances required by the University before any physical, face-to-face activities can be undertaken with research participants. The University has issued 'restart' guidance on resuming research involving travel, in person contact with participants and/or external sites:

PDF version: <http://documents.manchester.ac.uk/display.aspx?DocID=50078>

Word version: <http://documents.manchester.ac.uk/display.aspx?DocID=50124>

Sponsor confirmation for your amendment does not supersede any 'restart' requirements set by the University. Chief Investigators must ensure that (1) the University 'restart' requirements have been met and (2) that face-to-face contact is permitted by University guidelines at the time of the planned activity (the guidance may change over time).

In the meantime, you may continue to get your approvals and share details of the amendments with the site (as outlined below).

Submission of Amendment – Next Steps:

1. Now that the Amendment Tool has been authorised, you need to generate the final pdf version of the tool. Open the Amendment Tool and click '*lock for submission*' to generate the pdf. To submit the amendment, use the [online submission portal](#) (this requires a separate account/login to your main IRAS account).

2. Once submitted, you will receive an automated email confirmation. You should not expect to receive a categorisation email post-submission as this is included in the output section of the amendment tool. Please refer to the 'submission guidance tab' of your amendment tool for further information regarding the amendment category and requirements for notifying the participating organisations hosting the research project (R&D office and local research team). You can also find detailed guidance on HRA webpage:
<https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx#What-happens-after>. For information, the national directory of NHS R&D offices can be found at: <http://www.rdforum.nhs.uk/content/contact-details/>
3. Once the amendment has been approved by the REC/HRA please send a copy of the Amendment Tool, any amended study 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,

Scott.

Have you downloaded our new Governance Pack? For information on our processes from initial application through to Ending your study, and everything in between (Amendments/Sponsor Green Light/Training for Researchers) including guides and templates, please use the link below:

www.staffnet.manchester.ac.uk/bmh/research/ethics-and-regulatory-support/sponsorship-approval/

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