

Anthony Marshall

From: MHS Ethics Applications
Sent: 31 January 2025 14:59
To: Anthony Marshall
Cc: MHS Ethics Applications; Diane Escott
Subject: Amendment SA31_IRAS 64202_sponsor approval
Attachments: Amendment_Tool_v1_6_06Dec21_BSRBR-RA(IRAS_64202) SA31_30012025.xlsm;
What Happens after My Amendment has been reviewed by the Research Governance Team.pdf

Dear Anthony,

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

IRAS ID: 64202

Amendment Number and Date: SA31, 31/01/2025

Many thanks for sending notification of the proposed amendment to this study. This email confirms sponsor support for this amendment.

What Happens Next?

There are a number of actions and outcomes following the submission of your amendment via the online portal which are dependent on the outcome of Section 4 of the Amendment Tool. Please read **all sections below**, along with the guidance in the submission tab of your amendment tool, and the attached document: **What Happens after My Amendment has been reviewed by the Research Governance Team?**

Research Governance Team on behalf of the sponsor	<ul style="list-style-type: none">Now we have approved your amendment there are no further actions for us concerning <u>reviewing</u> your amendment. This email is confirmation that there are no issues from a governance perspective and <u>the amendment is approved</u>.However (if applicable and dependant on the category of amendment) if you wish to request further guidance on response queries from the REC/HRA when they have reviewed your amendment we will assist where it is within our remit as governance sponsor. Please also note, that if we see queries which may require sponsor input then we may contact you before you respond to the NHS REC/HRA.
Research Team	<ol style="list-style-type: none">Now that the Amendment Tool has been authorised (attached) you need to generate the final pdf version of the tool. Open the Amendment Tool and click '<i>lock for submission</i>' to generate the pdf.Please review the attached document <u>What Happens after My Amendment has been reviewed by the Research Governance Team?</u> to ensure you are following the correct process dependant on the information in the 'submission guidance' tab of your amendment tool.To submit the amendment (as applicable), use the IRAS online submission portal (this requires a separate account/login to your main IRAS account).Once submitted, you will receive an automated email confirmation. Please refer to the 'submission guidance tab' of your amendment tool for further information regarding the amendment category and requirements for notifying the

	<p>participating organisations hosting the research project (R&D office and local research team).</p> <ol style="list-style-type: none"> Please send any automated emails from the NHS REC/HRA to us throughout the amendment process, for our records (fbmhethics@manchester.ac.uk). After you have submitted your amendment, you now share your completed Amendment Tool with confirmation of amendment category and, if applicable, amended documents with relevant participating NHS organisations in England and/or Wales (there are email templates available here for this process: https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx#What-happens-after). Note: If you have Northern Ireland or Scottish organisations involved in your study you should follow the specific guidance at the same link. If applicable, 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)/emails to FBMHethics@manchester.ac.uk – these can be sent electronically. This is so that the sponsor study file can be updated. Once the REC opinion and HRA outcome has been received please ensure that you send regulatory approvals (NHS REC/HRA as applicable) to the participating sites (R&D office and local research team) as per the REC/HRA email instructions. <u>If applicable</u> make arrangements to update your CPMS record with any related changes, as required. Note: CPMS is an online database used for the management of all study records within the National Institute for Health Research (NIHR) Clinical Research Network (CRN) Portfolio. <p>10. IMPORTANT NOTE FOR HUMAN TISSUE STUDIES:</p> <p>All studies involving human tissue should be registered with the University’s Research Governance Officer (Human Tissue) diane.escott@manchester.ac.uk. If you have not done so already, you should use the HTA Survey Form (http://documents.manchester.ac.uk/display.aspx?DocID=8649) to register your samples. If the amendment you have submitted means a change to the information you gave when you registered your samples you should consider if any alterations are required to your original registration, and if so, make the appropriate changes. There is guidance on the registration process and managing human tissue on StaffNet: https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/human-tissue/.</p>
NHS /HSC organisations in all Nations	<p><i>As above, 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).</i></p> <ul style="list-style-type: none"> Research Teams should not expect to receive a letter or email of confirmation from NHS/HSC organisations before implementing the amendment. If all relevant regulatory approvals are in place and there has been no objection from site, category A and B amendments can be implemented after 35 days. Category C amendments can be implemented as soon as any regulatory approvals are received – there is no need to wait 35 days.

- Category A and B amendments may be implemented sooner than 35 days in cases where all regulatory approvals have been issued and where the NHS/HSC organisation has confirmed that the amendment may be implemented prior to this date.
- If applicable, upon receipt of the amendment, the coordinating function of the lead nation will notify the coordinating function of any other participating nation(s).

You can find more information here:

<https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx#What-happens-after> and by checking your amendment tool.

BW,
Carlyn

Carlyn Murray (pronounced: Car-Lyn) (she/her) | Research Governance Support Assistant

I am available via email and Teams when working from home, Monday, Wednesday Thursday and Friday. Tuesday is my office day.
Faculty of Biology, Medicine and Health | 4.64 Simon Building | The University of Manchester

Have you downloaded our updated 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/

Website: [FBMH Research Governance Website](http://fbmh-research-governance-website)

Twitter: [@fbmh_ethics](https://twitter.com/fbmh_ethics)