

## Anthony Marshall

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**From:** MHS Ethics Applications  
**Sent:** 24 June 2022 16:38  
**To:** Anthony Marshall  
**Cc:** MHS Ethics Applications  
**Subject:** Substantial Amendment 29, IRAS 64202, REC 00/8/53, sponsor approval  
**Attachments:** Authorised\_Amendment\_Tool\_v1\_6\_06Dec21\_BSRBR-RA(IRAS\_64202) SA29\_19052022.xlsm; What Happens after My Amendment has been reviewed by the Research Governance Team.docx

Dear Anthony,

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

**REC Ref: 00/8/53**

**IRAS ID: 64202**

**Amendment Number and Date: Substantial Amendment 29, 19/05/2022**

Many thanks for sending notification of the proposed amendment to this study. Based on my initial review, and your subsequent confirmation of changes made following feedback, I can confirm 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"><li>• 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>.</li><li>• 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.</li></ul>
Research Team	<ol style="list-style-type: none"><li>1. 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.</li><li>2. Please review the attached document <b><u>What Happens after My Amendment has been reviewed by the Research Governance Team?</u></b> to ensure you are following the correct process dependant on the information in the 'submission guidance' tab of your amendment tool.</li><li>3. To submit the amendment (as applicable), use the IRAS <a href="#">online submission portal</a> (this requires a separate account/login to your main IRAS account).</li><li>4. 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</li></ol>

	<p>participating organisations hosting the research project (R&amp;D office and local research team).</p> <ol style="list-style-type: none"> <li>Please send any automated emails from the NHS REC/HRA to us throughout the amendment process, for our records (<a href="mailto:fbmhethics@manchester.ac.uk">fbmhethics@manchester.ac.uk</a>).</li> <li>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: <a href="https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx#What-happens-after">https://www.myresearchproject.org.uk/help/hlpamendmentsresearch.aspx#What-happens-after</a>). <b>Note:</b> If you have Northern Ireland or Scottish organisations involved in your study you should follow the specific guidance at the same link.</li> <li>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 <a href="mailto:FBMHethics@manchester.ac.uk">FBMHethics@manchester.ac.uk</a> – these can be sent electronically. This is so that the sponsor study file can be updated.</li> <li>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&amp;D office <b>and</b> local research team) as per the REC/HRA email instructions.</li> </ol> <p><b>9. IMPORTANT NOTE FOR HUMAN TISSUE STUDIES:</b></p> <p>All studies involving human tissue should be registered with the University’s Research Governance Officer (Human Tissue) <a href="mailto:diane.escott@manchester.ac.uk">diane.escott@manchester.ac.uk</a>. If you have not done so already, you should use the HTA Survey Form (<a href="http://documents.manchester.ac.uk/display.aspx?DocID=8649">http://documents.manchester.ac.uk/display.aspx?DocID=8649</a>) 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: <a href="https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/human-tissue/">https://www.staffnet.manchester.ac.uk/rbe/ethics-integrity/human-tissue/</a>.</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&amp;D office and local research team).</i></p> <ul style="list-style-type: none"> <li>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.</li> <li>Category C amendments can be implemented as soon as any regulatory approvals are received – there is no need to wait 35 days.</li> <li>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.</li> </ul>

- 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.

Best wishes,  
Vivian

### Research Governance Clinic Slots Available

Clinic appointments are available every **Thursday at 1pm, 1:20pm, 1:40pm and Friday at 10am, 10.20am and 10:40am via Zoom/Teams for 20 minute slots**. If you have a general query, or something more specific to your study you would like to discuss with us please email [fbmhethics@manchester.ac.uk](mailto:fbmhethics@manchester.ac.uk) to book a slot. Please confirm the time and day from the above best suited to you and briefly outline the issue you wish to discuss, and one of the team will get back to you to confirm your place.

**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/](http://www.staffnet.manchester.ac.uk/bmh/research/ethics-and-regulatory-support/sponsorship-approval/)

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