

Dr Daniel McAuley
Imperial College London
QEOM, St Mary's Hospital, Praed Street
London
W2 1NY

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

01 July 2025

Dear Dr McAuley

**HRA and Health and Care
Research Wales (HCRW)
Approval Letter**

Study title:	Precision medicine Adaptive Network platform Trial in Hypoxaemic acutE respiratory failuRe
IRAS project ID:	1008743
Protocol number:	175151
REC reference:	25/NW/0103
Sponsor	Imperial College London

I am pleased to confirm that [HRA and Health and Care Research Wales \(HCRW\) Approval](#) has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the “Information to support study set up” section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see [IRAS Help](#) for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?

HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to [obtain local agreement](#) in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document “[After Ethical Review – guidance for sponsors and investigators](#)”, issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The [HRA website](#) also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?

Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **1008743**. Please quote this on all correspondence.

Yours sincerely,

Tina Cavaliere

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Ruth Nicholson, Imperial College London*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

<i>Document</i>	<i>Version</i>	<i>Date</i>
Contract/Study Agreement template [PANTHER mNCA_July_2022 2.1 ICL Template_14.03.2025]		
Cover Letter [PANTHER Covering letter for REC_MHRA v3.0 17.03.2025]	3.0	17 March 2025
Cover Letter [PANTHER Covering letter RFI_REC_MHRA v1.0 17.06.2025]	1.0	17 June 2025
EudraCT PDF [Medicines Information]		17 March 2025
GP/consultant information sheets or letters [PANTHER GP letter V1.0 07.11.24]	1.0	07 November 2024
Investigator Brochure/SmPC [Baricitinib_SmPC_(Olumiant)_updated 25.09.2023]	1.0	29 September 2023
Investigator Brochure/SmPC [Simvastatin SmPC_updated 31.07.2023]	1.0	31 July 2023
Letter from funder [PANTHER_Funding Award Letter 23.02.2024]	1.0	23 February 2024
Letter from sponsor [172256 PANTHER Sponsorship approval]	N/A	10 March 2025
Letter from statistician [PANTHER Stats Engagement Letter signed EW RP VC]	1.0	07 March 2025
Miscellaneous [ATS PHIND ARDS phenotypes]	N/A	11 May 2024
Miscellaneous [PANTHER NIHR Peer Review]	1.0	23 February 2024
Organisation Information Document [PANTHER OID 24.03.2025 Final]		
Participant information and informed consent form [PANTHER Privacy Notice V1.0 06.02.2025]	1.0	06 February 2025
Participant information and informed consent form [PANTHER Telephone Agreement Form V1.0 06.02.25]	1.0	06 February 2025
Participant information and informed consent form [PANTHER_Privacy Notice_V2.0_14042025 TC]	2.0	14 April 2025
Participant information and informed consent form [PANTHER_Privacy Notice_V2.0_14042025 Clean]	2.0	14 April 2025
Participant information and informed consent form [PANTHER_PIS_V2.0_14042025 TC]	2.0	14 April 2025
Participant information and informed consent form [PANTHER_PIS_V2.0_14042025 Clean]	2.0	14 April 2025
Participant information and informed consent form [PANTHER_PIS Sum_V2.0_14042025 TC]	2.0	14 April 2025
Participant information and informed consent form [PANTHER_PIS Sum_V2.0_14042025 Clean]	2.0	14 April 2025
Participant information and informed consent form [PANTHER_PIS ProLR Sum_V2.0_14042025 TC]	2.0	14 April 2025
Participant information and informed consent form [PANTHER_PIS ProLR Sum_V2.0_14042025 Clean]	2.0	14 April 2025
Participant information and informed consent form [PANTHER_PerLR Sum_V2.0_14042025 TC]	2.0	14 April 2025
Participant information and informed consent form [PANTHER_PerLR Sum_V2.0_14042025 Clean]	2.0	14 April 2025
Project Information - PDF [ProjectStudyInformation]		17 June 2025
Proof of Insurance [2024 Verification Certificate]	N/A	09 August 2024
Protocol [PANTHER UK Region Specific Appendix V1.0 03.03.2025]	1.0	03 March 2025
Protocol [PANTHER Subphenotype Appendix_ARDS V1.0]	1.0	06 February 2025

06.02.2025]		
Protocol [PANTHER Statistical design appendix V1.0 19.02.2025]	1.0	19 February 2025
Protocol [PANTHER Master Protocol V1.0 03.03.2025]	1.0	03 March 2025
Protocol [PANTHER Intervention Appendix_Baricitinib V2.0 11.06.2025_Clean]	2.0	11 June 2025
Protocol [PANTHER Intervention Appendix_Baricitinib V2.0 11.06.2025_TC]	2.0	11 June 2025
Protocol [PANTHER Intervention Appendix_Simvastatin V2.0 11.06.2025_Clean]	2.0	11 June 2025
Protocol [PANTHER Intervention Appendix_Simvastatin V2.0 11.06.2025_TC]	2.0	11 June 2025
Protocol [PANTHER Master Protocol V2.0 11.06.2025_Clean]	2.0	11 June 2025
Protocol [PANTHER Master Protocol V2.0 11.06.2025_TC]	2.0	11 June 2025
REC Application Form [Ethics]		17 June 2025
Response to Request for Further Information [PPI feedback 5-PANTHER PIS Full V0.2 041024]	1.0	13 November 2024
Response to Request for Further Information [PPI feedback 4-PANTHER PIS Full V0.2 041024]	1.0	12 November 2024
Response to Request for Further Information [PPI feedback 3-PANTHER PIS Full V0.2 041024]	1.0	11 November 2024
Response to Request for Further Information [PPI response on PIS]	1.0	11 November 2024
Response to Request for Further Information [PANTHER Response to reviewer comments_final]	1.0	01 March 2024
Response to Request for Further Information [PANTHER NIHR Peer Review 23.02.2024]	1.0	23 February 2024
Response to Request for Further Information [PANTHER Study Risk Assessment_v3.0 12-Jun-2025]	3.0	12 June 2025
Response to Request for Further Information [ICL GDPR Wording Approval]	1.0	07 May 2025
Schedule of Events or SoECAT [Funder Export_1008743_SoECAT_PANTHER]		
Suitability of the investigator/Investigator CV [CV short Danny McAuley 25.11.2024]	N/A	25 November 2024
Validated questionnaire [Social outcome set_SF36]	1.0	09 December 2024
Validated questionnaire [MoCA-Test-English_2009]	7.1	02 January 2009
Validated questionnaire [Impact-of-Event-Scale]	1.0	09 December 2024
Validated questionnaire [Hospital Anxiety and Depression Scale (HADS)]	1.0	09 December 2024
Validated questionnaire [EQ-5D-5L Paper Telephone v1.3]	1.3	01 January 2012

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
Research activities and procedures as per the protocol and other study documents will take place at participating NHS organisations.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study in accordance with the contracting expectations detailed.	An Organisation Information Document has been submitted but the sponsor is intending to use a separate agreement. The sponsor has supplied the unmodified model agreement and intends to use this with participating NHS organisations.	Study funding arrangements are detailed in the Organisation Information Document.	A Principal Investigator should be appointed at participating NHS organisations.	Where an external individual who does not already hold an NHS employment contract will be conducting any of the research activities that will be undertaken at this site type then they would be expected to hold an Honorary Research Contract. External staff holding pre-existing NHS employment contracts should obtain a Letter of Access. These should confirm Occupational Health Clearance. These should confirm enhanced DBS checks and appropriate barred list checks.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.

The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.