Prof Janet Powell
Professor of Vascular Biology and Medicine
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Email: approvals@hra.nhs.uk

15 October 2024

Dear Prof Powell

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

Study title:	**Women's Aneurysm Research: Repair Immediately or Routine Surveillance, Trial and Registry**
IRAS project ID:	**341602**
Protocol number:	**24CX8836**
REC reference:	**24/NW/0265**
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 **341602**. Please quote this on all correspondence.

Yours sincerely,

Tina Cavaliere

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Cheuk F Wong, Imperial College London*

List of Documents

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

Document	*Version*	*Date*
Contract/Study Agreement template [Model agreement for non-commercial research]	2.3	28 July 2022
Covering letter on headed paper [cover letter]		07 August 2024
Covering letter on headed paper [IRASamendments]	2.0	03 October 2024
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Imperial liability]		01 August 2023
GP/consultant information sheets or letters [GPletter]	1.0	18 June 2024
Interview schedules or topic guides for participants [Patient Decision Aid highlighted]	1.1	16 September 2024
Interview schedules or topic guides for participants [Patient Decision Aid clean]	1.1	16 September 2024
IRAS Application Form [IRAS_Form_08082024]		08 August 2024
Letter from funder [BHF letter of offer]		20 September 2023
Letter from sponsor [Sponsor letter]		20 June 2024
Letter from statistician [WARRIORS protocol clean]	1.1	14 September 2024
Letter from statistician [Protocol appendices]	1.0	18 June 2024
Organisation Information Document [Organization doc]	1-	08 April 2024
Other [Involvement of patients & public for design]	1.0	12 August 2024
Other [WARRIORS protocol]	1.0	24 June 2024
Other [Response toREC/HRA_table]		02 October 2024
Participant consent form [ICF WARRIORS main tracked]	1.1	18 September 2024
Participant consent form [ICF WARRIORS main clean]	1.1	18 September 2024
Participant consent form [QRI patient CONSENT tracked]	2.0	18 September 2024
Participant consent form [QRI patient CONSENT clean]	2.0	18 September 2024
Participant consent form [QRI staff CONSENT tracked]	2.0	18 September 2024
Participant consent form [QRI staff CONSENT clean]	2.0	18 September 2024
Participant consent form [WARRIORS consent]	1.0	18 June 2024
Participant consent form [QRI consent patient]	1.0	18 June 2024
Participant consent form [QRI consent staff]	1.0	18 June 2024
Participant information sheet (PIS) [PIS main]	1.0	24 June 2024
Participant information sheet (PIS) [PIS main trial traKCED]	1.1	18 September 2024
Participant information sheet (PIS) [pis MAIN TRIAL CLEAN]	1.1	18 September 2024
Participant information sheet (PIS) [WRI patient PIS tracked]	2.0	19 September 2024
Participant information sheet (PIS) [QRI patient PIS clean]	2.0	19 September 2024
Participant information sheet (PIS) [tracked]	2.0	21 September 2024
Participant information sheet (PIS) [QRI staff PIS clean]	2.0	21 September 2024
Research protocol or project proposal [WARRIORS protocol tracked]	1.1	14 September 2024
Schedule of Events or SoECAT [WARRIORS SoECAT]		29 November 2022
Summary CV for Chief Investigator (CI) [CV Powell]		21 March 2024
Validated questionnaire [EQ5D-5L]		
Validated questionnaire [HADS questionnaire]		

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.