North West - Liverpool Central Research Ethics Committee
2 Redman Place
Stratford
London
E20 1JQ

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

15 October 2024

Prof Janet Powell
Professor of Vascular Biology and Medicine
Imperial College London
Charing Cross Hospital, Fulham Palace Road
London
W6 8RF

Dear Prof Powell

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

Thank you for your letter of , responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation [as revised], subject to the conditions specified below.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a public registry before the first participant is recruited and no later than six weeks after. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

A 'public registry' means any registry on the WHO list of primary registries or the ICMJE list of registries provided the registry facilitates public access to information about the UK trial.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

Where a deferral is agreed we expect the sponsor to publish a minimal record on a publicly accessible registry. When the deferral period ends, the sponsor should publish the full record on the same registry, to fulfil the condition of the REC favourable opinion.

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Where the study is registered on ClinicalTrials.gov, please inform deferrals@hra.nhs.uk and the Research Ethics Committee (REC) which issued the final ethical opinion so that our records can be updated.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter. Where a deferral is agreed, a minimum research summary will still be published in the research summaries database. At the end of the deferral period, we will publish the full research summary.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: Research summaries - Health Research Authority (hra.nhs.uk)

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document “After ethical review – guidance for researchers” gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at Managing your approval - Health Research Authority (hra.nhs.uk)

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
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
IRAS Checklist XML [Checklist_03102024]		03 October 2024
Letter from funder [BHF letter of offer]		20 September 2023
Letter from sponsor [Sponsor letter]		20 June 2024
Letter from statistician [Protocol appendices]	1.0	18 June 2024
Letter from statistician [WARRIORS protocol clean]	1.1	14 September 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 [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 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 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
Summary CV for Chief Investigator (CI) [CV Powell]		21 March 2024

Validated questionnaire [EQ5D-5L]		
Validated questionnaire [HADS questionnaire]		

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: Quality assurance - Health Research Authority (hra.nhs.uk)

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: Learning - Health Research Authority (hra.nhs.uk)

IRAS project ID: 341602 Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

Tina Cavaliere (on behalf of)

Mr Paul Mooney
Chair

Email: liverpoolcentral.rec@hra.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

After ethical review guidance for sponsors and investigators – Non CTIMP Standard Conditions of Approval]

Copy to: Cheuk F Wong, Imperial College London