**Participant Information Sheet for STAFF**

**WARRIORS Quintet Recruitment Intervention Study**

**Women’s Aneurysm Research: Repair Immediately Or Routine Surveillance (WARRIORS) trial**

We are inviting you to take part in the Quintet Recruitment Intervention Study (QRIS) which is integrated into the WARRIORS randomised controlled trial (RCT). The QRIS aims to understand and address recruitment issues in WARRIORS as the trial progresses.

This information sheet explains the purpose and conduct of the QRIS to enable you to make an informed decision about participation. Please ask a member of the QRIS team if there is anything that is unclear or if you would like more information. Contact details shown at the end of this information sheet. Thank you for considering our request.

**What is the purpose of the study?**

Women are under-represented in nearly all cardiovascular surgery RCTs. Therefore, a trial such as WARRIorS, which recruits only women, provides a particular challenge. The WARRIORS QRIS aims to optimise the provision of clear and balanced information about patients’ treatment options and the possibility of participation in the WARRIORS RCT. To achieve this the QRIS seeks to rapidly understand and address recruitment issues usingseveral methods whilst the RCT is underway. We are asking if you will help with two of these. Specifically, we would like to audio-record appointments where WARRIORS is discussed with eligible patients, and interview professionals working on the RCT.

One way to improve our knowledge is to audio-record the conversations you have with patients about your possible participation in the WARRIORS trial. This will help us to understand better how the information about the study is presented, and how we could improve the way we discuss the study with patients.

Interviewing you will also help us to understand how patients come to their decision and if there are any barriers to joining in and staying in the study, which could be overcome. The information provided will be used to see if we can improve the presentation, style and content of information provided by recruiters and to understand any hidden challenges.

***Why have I been invited?***

You have been invited because of your involvement in WARRIORS. Your role may encompass identifying eligible patients, discussing treatments with patients, recruiting eligible patients, or you may have responsibility for oversight or conduct of WARRIORS at a site-level or study-wide level.

***Do I have to take part?***

No. It is entirely up to you to decide whether to take part in the QRIS. If you change your mind you can withdraw at any time and without giving a reason.

If you do decide to take part, you will be asked to sign a consent form (paper or electronic), which includes separate clauses for audio-recording consultations and interviews. Audio-recording will only be carried out when patient consent is also obtained. Information for patients will be provided in a separate information sheet. You are also free to refuse to answer any specific interview question, or to withdraw from an interview or training session without giving a reason.

If you do decide to withdraw from the study or you want to discuss this option, you should contact the study investigator using the contact at the end of this information sheet.

**What will happen to me if I take part?**

Taking part in the Recruitment Study will involve all or some of the following:

1. Audio-recording recruitment discussions: We will ask you to audio-record conversations you have with patients about participating in WARRIORS. These may include initial discussions about treatment options as well as any subsequent discussions and the patient's decision about trial entry. We will provide you with an audio-recorder to do this.
2. Being Interviewed: We may invite you to attend one or more interviews with a qualitative researcher to discuss your views on the WARRIORS study. This will normally be a telephone interview, although we can do in-person interviews. We will arrange interviews at a time (and place) that is convenient to you. We will audio-record your interview if you consent, so that the researchers can listen to it again and make a transcript of the discussion.
3. You may be invited to attend individual and group recruitment feedback/training sessions, based on the QRIS research findings. We usually do these by telephone, in-person or by video-link. This training will be supportive, with the aim of sharing good practice and jointly devising solutions to recruitment challenges.

You will be asked to sign a consent form indicating whether or not you give permission for each of the above activities. The consent forms will be either on paper, and you will get a copy of the form to keep or electronically when you will receive a copy of your form by e-mail. You do not have to agree to all or any of these activities.

What are the possible risks or disadvantages of taking part?

There are no physical risks to taking part. If you audio-record recruitment discussions with potential WARRIORS participants, you may feel the presence of the recorder. Our experience is that recruiters report that they rapidly cease to be aware of it.

Interviews normally take between 30-45 minutes of your time. We will ensure this is arranged at your convenience. You may be asked to take part in more than one interview over the course of the WARRIORS trial, although taking part in one interview does not obligate you to further interviews.

**What are the possible benefits of taking part?**

If you are involved in recruiting patients to WARRIORS, you may receive recruitment support delivered individually or as part of a group and will have opportunities to discuss any difficulties you may be experiencing with the recruitment process. You may receive individually tailored feedback from your consultations, if you would like this, based on the analysis. Some people find that taking part in interview analysis can help them to reflect on and improve their practices.

**What happens when the QRI Study stops?**

Your ongoing participation in the WARRIORS trial is will continue..

When the study stops, the research team will analyse the information obtained and use it to try and improve the ways (written and verbal) in which we communicate with patients.

**PART 2**

***What if something goes wrong?***

It is very unlikely that you will be harmed by taking part in this type of research study. Imperial College London holds insurance policies which apply to this study. If you experience harm or injury, as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator.

You should contact the study investigator using the contact details given at the end of this information sheet.

If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team (rgit@imperial.ac.uk).

**How will we use information about you?**

We will need to use information from you for this research project. This information will include your:

* Initials
* Age
* Gender
* Role in the clinical care team

People within Imperial College and the University of Leicester study teams (see section sharing your information with others) will use this information to do the research or to check your records to make sure that research is being done properly and the information held (such as contact details) is accurate.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

After the interview, the recording from the interviews will be uploaded to a computer and converted into written records of the interview or clinic consultation (known as transcripts).

The transcripts are word documents which will be analysed. The word documents will be anonymised, which means that no one will be able to identify the fact that you gave this interview.

After preparation of the transcripts, recordings from interviews and consultations will be deleted from the recording devices and any computers they might have been uploaded to in preparing the transcripts.

Summaries of anonymised findings will be presented to all those involved in the study, but no identifiers of individuals or clinical centres will be shown in presentations or reports.

Patient information sheets (PIS), consent forms and the study protocol in each country will be examined after we have the findings from the semi-structured interviews and recruitment appointments to identify aspects that might be confusing.

A plan of action to improve recruitment will be proposed.

Imperial College London is the sponsor for this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it appropriately.

The transcripts will be stored by Imperial College London. Imperial College London will keep your personal data for:

* 10 years after the study has finished in relation to data subject consent forms.
* 10 years after the study has completed in relation to primary research data.

The study is expected to finish in summer 2026.

For more information / confirmation regarding the end date please contact the study team, see **Where can you find out more about how your information is used?** for contact information.

**Legal Basis**

As a university we use personally identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research.  This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Our legal basis for using your information under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, is as follows: Imperial College London - “performance of a task carried out in the public interest”); Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/)

Where special category personal information is involved (most commonly health data, biometric data and genetic data, racial and ethnic data etc.), Imperial College London and University of Leicester rely on “scientific or historical research purposes or statistical purposes

**International Transfers**

There may be a requirement to transfer information to countries outside the United Kingdom (for example, to a research partner, either within the European Economic Area (EEA) or to other countries outside the EEA. Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a UK adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient research partner that incorporates UK approved standard contractual clauses or utilise another transfer mechanism that safeguards how your personal data is processed.

**Sharing your information with others**

We will only share your personal data with certain third parties for the purposes referred to in this participant information sheet and by relying on the legal basis for processing your data as set out above.

* Other Imperial College London employees (including staff involved directly with the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc.), Imperial College London agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.
* University of Leicester (Dr R Evley) who will oversee the analysis and interpretation of the data. The data to be shared include your age, gender and role in the clinical care team. Only data essential for the research study or as part of certain secondary activities which may include support functions, internal audits, ensuring accuracy of contact details etc., will be shared.

Although what you say in the interview is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons. For example, if the principal investigator becomes aware of a safeguarding disclosure such as any suspected or alleged abuse of vulnerable adults during this research, confidentiality will be broken and the disclosure reported to the lead safeguarding officer at the local NHS Trust.

**Potential use of study data for future research**

When you agree to take part in a research study, the information collected either as part of the study or in preparation for the study (such as contact details) may, if you consent, be provided to researchers running other research studies at Imperial College London and the University of Leicester and in other organisations which may be universities or organisations involved in research in this country or abroad. Your information will only be used to conduct research in accordance with legislation including the GDPR and the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/).

This information will not identify you and will not be combined with other information in a way that could identify you, used against you or used to make decisions about you.

**What are your choices about how your information is used?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have because some research using your data may have already taken place and this cannot be undone.

We need to manage your records in specific ways for the research to be reliable. This means that we may not be able to let you see or change the data we hold about you if this could affect the wider study or the accuracy of data collected.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information:

* [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
* by asking one of the research team
* by sending an email to [WARRIORS@imperial.ac.uk](mailto:WARRIORS@imperial.ac.uk)
* by writing to us at Imperial Clinical Trials Unit, 1st Floor, Stadium House, Wood Lane, London, W12 7RH
* by ringing us on [**phone number**]

**Complaint**

If you wish to raise a complaint about how we have handled your personal data, please contact the study investigator (details at the end of this information sheet).

Following our response, if you are not satisfied please contact Imperial College London’s Data Protection Officer via email at [dpo@imperial.ac.uk](mailto:dpo@imperial.ac.uk), via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you remain unsatisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner’s Office (ICO)- via [www.ico.org.uk](http://www.ico.org.uk). Please note the ICO does recommend that you seek to resolve matters with the data controller (Imperial College London) first before involving them.

**What will happen to the results of the research study?**

The results (with all identifiable detail removed) may be published or presented and a clinical study report summarising study results will be prepared and sent to regulatory bodies. We will also prepare a newsletter to be sent to out to patients summarising the key outcomes of the study.

**Who is organising and funding the research?**

The WARRIORS studytrial is run by Imperial College London. Imperial College London is Sponsor for the research. This QRIS is organised in collaboration between Imperial College London and the University of Leicester. WARRIORS and the QRIS funded by the British Heart Foundation.

**Who has reviewed the study?**

This study has been reviewed and given favourable opinion by the British Heart Foundation, the Global Cardiovascular Research Funders Forum and Imperial College Research Governance and Integrity Team. This study was given a favourable ethical opinion for conduct in the NHS by Liverpool Central Research Ethics Committee.

**Study Contact details**

Please contact the study investigator (details below) if you have any concern:

* Name: Dr Rachel Evley
* Email: [rachel.evley@leicester.ac.uk](mailto:rachel.evley@leicester.ac.uk)
* Address: George Davies Centre, 15 Lancaster Road, Leicester, LE1 7HA
* Telephone: +44 (0)116 373 6857

**Thank you for taking the time to consider participating in this study.**

**If you accept to participate a copy of this information sheet and of the consent form will be given to you.**