**Participant Information Sheet for WARRIORS Quintet Recruitment Intervention study**

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

This study (known as the Recruitment Study) is an important part of the WARRIORS trial which looks at how doctors and nurses explain clinical research studies to patients.

The Recruitment Study involves:

• audio-recording your consultations in which WARRIORS is discussed, and/or

• taking part in an interview with a researcher after you have decided whether or not to join the main WARRIORS trial.

If you have already told your healthcare team whether or not you want to take part in WARRIORS when you receive this information sheet, the interview part alone will apply to you.

You can take part in the Recruitment Study regardless of whether or not you decide to take part in the main WARRIORS trial. The overall goal of the Recruitment Study is to improve how health care professionals give information about WARRIORS and other clinical studies to future patients.

Before you decide whether to take part in the Recruitment Study, it is important for you to understand what is involved. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. This information leaflet is just about the Recruitment Study and is being undertaken by our research partners from the University of Leicester.

You will have been given a separate information sheet explaining the main WARRIORS trial.

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

We are inviting you to take part in a study, which looks at how people make decisions about participating in clinical trials like WARRIORS. Currently we know little about how people, especially women, make decisions about whether or not to take part in clinical trials. In most cardiovascular disease trials women are poorly represented.

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

Interviewing you after you have made your decision about whether or not to take part in the WARRIORS trial will also help us to understand how you came to your decision.

Information from your interview and other women’s interviews will be used to see if there are any barriers to joining in and staying in the study, which could be overcome for future patients. The information provided will be used to see if we can improve the presentation, style and content of information provided by the recruiter and to understand any hidden challenges.

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

We are inviting you to take part in this study because you have had discussions (or will soon have discussions) with your doctors and nurses about joining a clinical study called the WARRIORS trial.

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

No, it is up to you to decide whether or not to take part. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision not to take part or a decision to withdraw will not affect the standard of medical care you receive or your legal rights. You can still take part in the WARRIORS trial without taking part in this Recruitment Study.

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 below:

* Name: Dr Rachel Evelyn

Email: rachel.evley@leicester.ac.uk

Address: George Davies Centre, 15 Lancaster Road, Leicester, LE1 7HA

* Telephone: +44 (0)116 373 6857

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

Taking part in this study will involve two optional things:

1. **- Audio-recording your consultations with doctors and nurses -** We will ask your permission to audio-record all the consultations where the WARRIORS trial and your treatment options are discussed, until you have chosen whether or not to take part in the WARRIORS trial.
2. **An interview with a researcher** - After you have made a decision about whether or not to take part in the WARRIORS trial, we may invite you to take part in an interview. We usually do this by telephone. The researcher is interested in how you came to your decision. Please be assured that whilst interested in your decision, the researcher will not question it or try to get you to change it. If you agree, your interview with the researcher will be audio-recorded.

You may wish to take part in both, one or none of the above.

You will be asked to sign a consent form for each of the options above 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. It is possible that talking about issues related to health and clinical care can cause some people anxiety. If this happens, the interview can be paused or stopped, and there will be no obligation to continue.

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

We cannot promise the Recruitment Study will help you directly, but the information we get will help us to improve the ways we communicate information about the WARRIORS trial and similar clinical studies in the future.

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

Your ongoing health care is in no way dependent on your participation in the Recruitment Study. You will continue to receive appropriate care when the Recruitment Study comes to an end.

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.

The normal National Health Service mechanisms are also available to you. The Patient Advice and Liaison Service (PALS) is an independent source of information on studies and also a route to raise complaints about treatment in the NHS.

The PALS office at the hospital can be reached using the below contacts:

* (Insert local PALS office contacts)

If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team.

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

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

* initials
* age
* postcode
* ethnic origin
* Highest educational achievement
* First language

People within the College and study team (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. In other words, no one will be able to identify the fact that you gave this interview.

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 UK Policy Framework for Health and Social Care Research.

**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 similar 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.

Where special category personal information is involved (most commonly health data, biometric data and genetic 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 Epley) 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 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.

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
* 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, 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 trial is run by Imperial College London. Imperial College London is Sponsor for the research. This Recruitment Study is organised in collaboration between Imperial College London and the University of Leicester. WARRIORS and the Recruitment Study is 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
* 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.**