A GENERAL INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form will give you important information about the why this study is being done, what will happen during the study, the risks and possible benefits. Please read it carefully. After you finish, talk with the researcher and ask questions. You may also want to talk to family, friends, your primary care doctor or other health care provider about joining this study. If you decide that you would like to take part in the study, you will be asked to sign this form and you will be given a copy of the signed form to keep.

B GENERAL INFORMATION ABOUT THE STUDY AND THE RESEARCHERS

B.1 Study Title

Title: "Inflammatory Biomarkers in Cardiovascular Disease"

B.2 Company or agency sponsoring the study

This study is sponsored by the "Institute of Cardiovascular Research."

B.3 Names of the researchers conducting the study

The principal investigator for this study is Dr. Sarah Johnson, and the research team includes Dr. Michael Anderson and Dr. Emily Davis.

C PURPOSE OF THIS STUDY

C.1 Why is this study being done?

This study is being conducted to deepen our comprehension of cardiovascular disease, a pervasive health issue that continues to pose significant challenges. Despite advancements in treatment, it remains a leading cause of morbidity and mortality worldwide. The primary objective of this research is to investigate the role of specific inflammatory cells, such as macrophages, and pro-inflammatory molecules, like C-reactive protein (CRP) and interleukin-6 (IL-6), in the context of cardiovascular disease. These inflammatory markers have been implicated in the progression of cardiovascular conditions. By precisely measuring and analyzing these biomarkers in the blood, we aim

to identify potential links between their levels and the severity of cardiovascular disease, as well as its associated complications, such as atherosclerosis and thrombosis. Moreover, this study seeks to unravel the complex interplay between inflammation and cardiovascular health, shedding light on the underlying mechanisms. It is anticipated that the findings from this investigation will have broader implications, potentially leading to the development of more accurate diagnostic tools, improved risk assessment models, and novel targeted therapies for individuals at risk of or currently affected by cardiovascular disease. Ultimately, our goal is to contribute to the reduction of cardiovascular disease's impact on public health and enhance the well-being of individuals by advancing our knowledge of its inflammatory components.

D INFORMATION ABOUT STUDY PARTICIPANTS

D.1 Why am I being asked to take part in this study?

You are being asked to take part in this study because you have been diagnosed with or are at risk of cardiovascular disease, and your participation will help us better understand the role of inflammatory markers in this condition.

D.2 How many subjects are expected to enroll in this study?

We anticipate enrolling 150 participants from this hospital/clinic into this study, with an additional 500 participants expected from other centers in a multicenter study.

D.3 Can I leave this study at any time?

Yes, you can leave the study at any time. However, if you decide to stop participating, we recommend discussing this decision with one of the research team members and your regular doctor to ensure your ongoing medical care is managed appropriately.

D.4 If I decide not to join this study, what other options do I have?

Instead of participating in this study, you have the option to receive standard of care treatment for your cardiovascular condition or explore other investigational products or procedures. Your healthcare provider can discuss these options with you, including their potential benefits and risks.

D.5 How long will I be in this study?

Your participation in this study is expected to last for approximately 6 months. There may be follow-up assessments or questionnaires, depending on the study's design.

E INFORMATION ABOUT STUDY PROCEDURES

E.1 What exactly will be done to me during this study? What kinds of research procedures will I receive if I agree to be in this study?

During this study, you will undergo blood draws to measure the levels of specific inflammatory cells and proteins. These procedures may take place at our research center, and some tests may be performed at home. A detailed schedule and description of study procedures will be provided to you upon enrollment.

F INFORMATION ABOUT RISKS AND BENEFITS

F.1 What risks will I face in this study?

Potential risks include discomfort or minor pain associated with blood draws, the possibility of infection at the site of the blood draw, and the potential for emotional distress related to your cardiovascular condition. These risks will be minimized, and we will provide appropriate medical care and support throughout the study.

F.2 What will the researchers do to protect me from these risks?

To minimize risks, trained healthcare professionals will perform blood draws using sterile techniques. We will closely monitor your health throughout the study and provide prompt medical attention if any adverse events occur.

F.3 What if I get sick or hurt or have other problems while in this study?

If you experience any health issues or concerns while participating in the study, please inform the research team immediately. We will provide appropriate medical care and support.

F.4 While I am in this study, can I also join other studies?

While participating in this study, you should not take part in any other research projects without approval from the study investigators to ensure your safety and well-being.

F.5 How can I benefit if I take part in this study? How could others benefit?

Your participation may not result in direct benefits to you, but the information obtained from this study may benefit future patients by advancing our understanding of cardiovascular disease and its treatment.

F.6 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, if we learn any new information during the study that could impact your willingness to continue, we will promptly inform you.

G INFORMATION ABOUT ENDING THE STUDY

G.1 If I wish to stop taking part in this study, what should I do?

If you decide to stop participating in the study, please discuss your decision with one of the research team members and your regular doctor to ensure appropriate post-study medical care.

G.2 Could there be any harm if I leave the study before it is finished?

Sudden withdrawal from the study could have adverse effects on your medical care, and any data collected up to that point may not be usable for research purposes.

G.3 Could the researchers take me out of the study even if I want to continue?

The investigator may decide to discontinue your participation in the study if it is believed to be in your best interest, if you fail to follow study instructions, if new safety information emerges, or for other important reasons determined by the investigator or sponsor.

H INFORMATION ABOUT THE COSTS

H.1 If I join this study, will it cost me anything?

Participation in this study will not incur any costs for you. Tests, procedures, and medications that are part of the research study will be provided at no charge.

H.2 Will my insurance company or will I be billed for any costs? If so, which costs and what will happen if my insurance doesn't cover these costs?

You and your insurance company will be responsible for any standard-of-care costs that are not related to the study. This may include co-payments, deductibles, or other expenses associated with routine healthcare. Costs directly related to the research study will not be billed to you.

H.3 Will I be paid or reimbursed for anything for taking part in this study?

You will be compensated for being in this study. Payment details will be provided to you upon enrollment.

H.4 Who could profit or benefit from the study results?

For your information, Dr. Sarah Johnson has a financial interest in this study as an unpaid consultant to the "Institute of Cardiovascular Research" but has no other financial interests or conflicts of interest related to this study.

I INFORMATION ABOUT CONFIDENTIALITY

I.1 How will my privacy be protected?

Your privacy will be protected by keeping your personal and medical information confidential. Only authorized personnel involved in the study will have access to your data.

I.2 What information about me may be seen by other people and why? Who are the others that might see it?

Only the research team and authorized regulatory authorities may access your study-related information. This information is needed to conduct the study and ensure its compliance with regulations.

I.3 What happens to the information about me after the study is over or if I leave the study early?

After the study is complete or if you leave the study early, your personal information will remain confidential. Research data will be stored securely for future analysis and reporting while protecting your identity.

J CONTACT INFORMATION

J.1 Who can I contact about this study?

For questions or concerns about the study, you can contact the principal investigator, Dr. Sarah Johnson.

J.2 Who can I contact about my rights as a research subject?

If you have questions about your rights as a research subject, please contact the Institutional Review Board (IRB)

J.3 Who can I contact if I think I have been injured as a result of this study?

If you believe you have been injured as a result of participating in this study, please contact the research team immediately, and appropriate medical care will be provided. You can also contact the Institutional Review Board (IRB) at [IRB Contact Information] to report any concerns related to the study.