Main Participant Information Sheet and Consent Form

Title	Preventing heart disease in women with non-traditional cardiovascular risk factors
Protocol Number	RES-19-0000-681A V1
Principal Investigator	*Dr Sarah Zaman*
Location	MonashHeart, Monash Health

Part 1 What does my participation involve?

1. Introduction

You are invited to take part in this research project: "Preventing heart disease in women with nontraditional cardiovascular risk factors". This is because you have been found to have one or more pregnancy-related risk factors for cardiovascular disease. These include a history of pregnancyrelated diabetes, high blood pressure or pre-eclampsia, a small-for-gestational-age baby and/or placental abruption. The research project is aiming to improve prevention of heart disease in women who have 'non-traditional' or pregnancy-related risk factors for cardiovascular disease.

This Participant Information Sheet and Consent Form tells you about the research project. It explains any tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor. Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read;

• Consent to take part in the research project;

• Consent to the tests and research that are described; and

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet and Consent Form to keep.

2. What is the purpose of this research?

The purpose of this study is to assess if a heart clinic designed to treat women only (a *Women's Heart Clinic*), can reduce the risk of women developing heart disease later in life. This involves reviewing women who are deemed to be at high risk of heart disease based on the presence of non-traditional cardiovascular risk factors. Traditional risk factors for heart disease are well known – these include high blood pressure, high cholesterol, diabetes, family history, being overweight and physically inactive. However, recent studies have shown that women can have 'nontraditional'

risk factors for heart disease. These can include a history of pregnancy-related diabetes, high blood pressure or pre-eclampsia, a small-for-gestational-age baby and/or placental abruption. Awareness of these risk factors in the general population and amongst doctors, is very low. However, all of these 'non-traditional' risk factors increase the chance of women developing heart disease later in life. The purpose of this study is to see if a *Women's Heart Clinic* can

effectively detect and treat these non-traditional risk factors. This is with the aim of preventing cardiovascular disease, such as heart attack and stroke, from developing later in life.

Women with a history of non-traditional risk factors who have been referred the Women's Heart Clinic will be invited to participate in this study. Information will be collected about risk factors for heart disease through a medical history, examination and standard of care blood tests to look at cholesterol levels, for example. Women with risk factors for heart disease will have these treated with lifestyle education and medications, when necessary and the effects of these measured within the Women's Heart Clinic after 1 year.

3. What does participation in this research involve?

If you agree to participate in the study, you will be asked to sign the Participant Information Sheet and Consent Form.

Your study participation will last for approximately 1 year from the time of agreeing to participate. Your participation will involve you participating in your usual recommended clinical care within the Women's Heart Clinic, where you will be reviewed by a doctor (cardiologist), a nurse and where necessary, a dietician. It will then involve 2 more visits: one visit 6 months later, and a final visit at one year after commencement of the study. If significant heart risk factors are detected, you may be seen more frequently, as clinically indicated. As part of the study, your personal and health information will be collected and recorded in a confidential, secure and de-identified manner in an online database. This enables us to monitor the effect of treatment within the Women's Heart Clinic on all study participants.

During your first visit to the Women's Heart Clinic, the following will be performed as part of your usual clinical care to assess your risk for heart disease and to guide standard of care treatment of these risk factors:

- Information about your age, sex, race, ethnicity and medical conditions of interest (prior high blood pressure, diabetes, high cholesterol, pregnancy-related conditions, medications) as well as diet, and exercise levels, will be collected. If necessary, your treating doctor and/or nurse will review your medical files.
- Your blood pressure, weight, height, waist circumference will be measured.
- Examination of your heart and lungs by the doctor will be performed.
- Fasting bloods as clinically indicated may be performed for your cholesterol levels, and/or basic screening for diabetes, kidney and liver function. These are all part of standard-ofcare blood tests to assess risk of heart disease.
- You may receive education about diet, exercise, risk factors for heart disease and medications all as clinically indicated and part of standard care.

During your first visit to the Women's Heart Clinic, the following in addition to standard care may be performed. However, if you do not want to undergo these additional tests you are still able to be part of the study:

- A brief survey about your understanding of your risk for heart disease (5 minute survey).
- Ultrasound assessment of cholesterol plaque build up in your neck arteries, and of artery function in the hand (approximately 5 minutes for each).

At 6 month and 12 month follow up visits to the Women's Heart Clinic, the following will be performed as part of standard of care treatment:

- Information about any new medical conditions, diet and exercise will be collected.
- Your blood pressure, weight, height, waist circumference will be measured.
- Examination of your heart and lungs by the doctor will be performed.
- Fasting bloods as clinically indicated may be performed for your cholesterol levels, and/or basic screening for diabetes, kidney and liver function. These are all part of standard-ofcare blood tests to assess risk and response to treatment.
- You may receive education about diet, exercise, risk factors for heart disease and medications all as clinically indicated and part of standard care.

At 6 month and 12 month follow up, the following in addition to standard care may be performed. However, as above, if you do not want to undergo these additional tests you are still able to be part of the study:

- A brief survey about your understanding of your risk for heart disease (5 minute survey).
- Ultrasound assessment of cholesterol plaque build up in your neck arteries, and of artery function in the hand (approximately 5 minutes for each).

4. What do I have to do?

If you agree to join this research project, you will have to provide the information required for the project, such as your medical history, and attend the Women's Heart Clinic.

5. Other relevant information about the research project

About 250 participants will join in this research study across 3 centres in Melbourne (Monash Health, Alfred Health and Cabrini Health), Victoria, Australia. It is expected that *150* participants will be enrolled into the research project here at *Monash Health.*

You will not receive payment for participating in this study.

You will not be charged for any of the tests and procedures which are performed solely for research purposes. The other tests are considered routine, standard of care tests and if you are Medicare eligible, most standard of care costs will be covered.

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we recommend that you inform them of your participation in this research project.

6. Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. This will not impact on you continuing to receive care by your treating doctor within the Women's Heart Clinic.

If you do decide to take part, you will be given this Participant Information Sheet and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating youor your relationship with *Monash Health*. If you choose to not take part or to withdraw, your treating doctor will continue to manage your condition as per standard of care.

7. What are the possible benefits of taking part?

As a result of being seen in the Women's Heart Clinic you will undergo a personalised review of your heart disease risk in a specialised way. This is all part of standard of care but is a new healthcare service that is being developed for women. You will be followed up in the clinic and undergo review and treatment by a cardiologist, nurse and dietician when needed, who may

assist in reducing your cardiovascular risk. As part of this research, you may be helping us treat other women in the future. You may not derive a direct benefit from participation in the study.

8. What are the possible risks and disadvantages of taking part?

Most of the information collected for this research project is standard medical history, with a blood test that is based on standard clinical care.. However, the main disadvantage is the time taken to participate in this risk assessment for heart disease. Since the majority of this study is conducted in the course of standard medical practice the risk of disadvantage of taking part is anticipated to be minimal. Risk related to participating in the additional study ultrasounds are also expected to be negligible as this is a safe, painless and non-invasive test that takes approximately 5 minutes to perform. These ultrasounds use a soft ultrasound gel. The risk of allergic reaction to this gel is extremely rare with only a few described cases from around the world.

9. What if I withdraw from this research project?

Withdrawal of study participation

You are free to stop your participation in this research project at any time. If you decide to withdraw from participation, please notify a member of the research team. This will not affect your ongoing treatment within the Women's Heart Clinic. Your de-identified information that has already been collected during the study prior to withdrawing your consent, will still be used together with the data collected from other participants in the study according to this Participant Information Sheet and Consent Form, and applicable laws.

10. What happens when the research project ends?

After the study is completed, asummary of the results may be published at conferences or in journals. If the results of the study are presented to the public, you will not be named. Any data shared will not identify you.

Part 2 How is the research project being conducted?

11. What will happen to the information about me?

By signing the consent form you consent to the study doctor and the relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential and securely stored. It will be disclosed only with your permission, or as required by law.

All of the collected data will be coded using a unique study number and your initials. No personal information, such as name and address will leave your treating hospital, and in all study information sent out from the clinic you will be identified with a code number only. All of your collected information will be kept by your treating hospital within the research department on a password-protected computer and locked filing cabinet within a restricted access research facility for 7 years after the end of the study. After the 7 year period your identifying information related to this study within the local hospital research department will be permanently deleted from the computer system and any hard copies will be destroyed.

Information about you may be obtained from your health records held at this institution and may be obtained from other health services for the purposes of research. By signing this consent form you agree to the study team accessing health records if they are relevant to your participation in this research project. Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities, Monash Health and representatives of the Monash Health Human Research Ethics Committee, or as required by law. By signing the consent section, you authorise access to this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

Information about your participation may be recorded in your health records.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information with which you disagree be corrected. However, please note that during the study, access to some personal data may be limited if it weakens the integrity of the research. You may have access to the personal data held by the study doctor at the end of the study. Please contact one of the researchers named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored within your treating Hospital. It will be disclosed only with your permission, or as required by law.

Monash Health, Alfred Health and Cabrini Health will own all data and results created during this study.

If you have concerns about the way your information is being handled you can make a complaint to the Office of the Australian Information Commissioner (OAIC) (refer to http://www.oaic.gov.au/ for more information).

12. Injury and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. Since the majority of this study is conducted in the course of standard medical practice compensation for injury or damage is anticipated to be minimal. Injury related to participating in the additional study questionnaire (5 minute questionnaire) is expected to be none. Injury related to participating in the additional study ultrasound is also expected to be negligible as this is a safe, painless and non-invasive test that takes approximately 5 minutes to perform. These ultrasounds use a soft ultrasound gel with a risk of allergic reaction to this gel extremely rare with only a few described such cases from around the world. **13. Who is organising and funding the research?**

This research project is being conducted by the study doctors within Monash Health, Alfred Health and Cabrini Health. It is not a sponsored study, and there is no industry support. Research grants delivered by Monash University are being used to fund some of this research. No member of the research team will receive a personal financial benefit from your involvement in this research project.

14. Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Monash Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2018)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15. Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study coordinator on 1300 643 278 or any of the following people: **Clinical contact person**

Name	*Dr Sarah Zaman*
Position	*Academic Cardiologist and Principle Investigator*
Telephone	*1300 643 278 or 9594 6666 (via switch)*
Email	*Sarah.zaman@monashhealth.org*

For matters relating to research at the site at which you are participating, the details of the local site complaints person are: **Complaints contact person**

Name	Deborah Dell
Position	03 9594 4611
Telephone	Deborah.Dell@monashhealth.org
Email	Deborah Dell

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Monash Health Ethics Committee
HREC Executive Officer	Deborah Dell
Telephone	03 9594 4611
Email	Deborah.Dell@monashhealth.org

Consent Form

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Principal Investigator	*Dr Sarah Zaman*
Location	MonashHeart, Monash Health

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *Monash Health* concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) ________________________________ Signature ____________________ Date ____________________

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

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USE THIS SECTION ONLY IF REQUIRED

An impartial witness signature is required if a participant is unable to read English (ICH GCP 4.8.9). The impartial witness should be present through the entire informed consent process.

Name of Witness* to Participant's Signature (please print) ________________________________ Signature Date ____________________

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Form for Withdrawal of Participation

Title	Preventing heart disease in women with non-traditional cardiovascular risk factors
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Principal Investigator	*Dr Sarah Zaman*
Location	MonashHeart, Monash Health

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *Monash Health.*

Name of Participant (please print)

_____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/Senior Researcher (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.