



CEDARS-SINAI MEDICAL CENTER.

Consent Form for the Women's Health Research Registry

This form contains a description of a research project. Please discuss the content of this form with the investigator before you agree to participate. Research studies include only people who choose to take part. Please take your time to make your decision and discuss it with your friends, family and/or physician. Remember that your participation is completely voluntary.

A. Who is conducting this study?

Dr. C. Noel Bairey Merz, Director, Women's Health and Preventive and Rehabilitative Cardiac Center and Dr. Beth Karlan, Director, Women's Cancer Research Institute, Department of Obstetrics and Gynecology, are conducting a research study sponsored by the Cedars-Sinai Women's Guild. Karen Nosakowski, Research Project Assistant, Samantha Lewis, Research Assistant, Maura Paul-Labrador, MPH, Joan Kirshner, RN, Research Coordinators, Jana Williams, Research Assistant and Amy Sriberg, Outreach Coordinator, will assist the investigators in this project. Dr. Bairey Merz, Ms. Nosakowski, Ms. Lewis, Ms. Paul-Labrador, Ms. Kirschner, Ms. Williams and Ms. Sriberg are located at 444 S. San Vicente, Los Angeles, CA 90048. Dr. Bairey Merz may be contacted at (310) 423-9680 and Ms. Nosakowski and Ms. Lewis can be reached at (310) 423-9224, Ms. Paul-Labrador, Ms. Kirschner and Ms. Williams can be reached at (310) 423-9666 and Ms. Sriberg can be reached at or (310) 423-4161. Dr. Beth Karlan is located at 8635 West Third Street, Suite 160, Los Angeles, CA 90048 and can be reached at (310) 423-3302.

B. Why am I invited to participate in this study?

You are being asked to take part in this study because you are a woman, of legal age, with or without a medical condition(s) who is willing to share your personal information to determine your eligibility in future research studies.

C. What is the purpose of this study?

This research is being done because women have been disproportionately under-represented in clinical research. Women represent 51% of the population, and the largest wave of over-45-year-old women in our country is coming with the aging of the baby boomers. These women are expected to live on average greater than 75 years, and yet we know very little about health and aging in women. Few of the many drugs approved by the Food and Drug Administration have been adequately tested in women. Most common health conditions experienced by both women and men are managed by treatments that have been developed and tested mostly in men.

The purpose of this study is to produce a registry of women with varying backgrounds and medical conditions (if any) for participation in future research trials. The registry will allow qualified investigators to identify potential participants for their studies, which will enable women to participate in research that may provide experimental treatments or medicines. Approximately 10,000 or more people will take part in this registry study at Cedars-Sinai Medical Center (CSMC). This is an ongoing study; this number represents anticipated enrollment over 5 years or more.

D. What will I be asked to do?

You will be asked to complete one questionnaire that is comprised of a brief medical and lifestyle history, including questions about your sexual orientation, pregnancy history, mental health, and family history. We will ask you questions in order to evaluate your current medical condition, if any, and to be able to match your information for future research studies. On average, the questionnaire may take 15 to 30 minutes to complete; however, due to the nature of the questions on the questionnaire, some individuals may take more time. If you feel uncomfortable answering any of the questions that we ask you, you are not required to answer them and the researcher will not insist that you respond. The questionnaire will ask you to provide information that identifies you, such as your name, address, contact phone numbers, etc. After the questionnaire is completed, the information will be transferred to a database. The personal information on the questionnaire, such as your name, will be removed from the medical information and kept separate for confidentiality purposes. If you agree to participate in this study, your information will be maintained in the study database for an indefinite length of time as the registry is an on-going project.

E. What are the possible risks and benefits of the study?

Risks - The possible risks associated with your participation in this study are embarrassment from filling out a sensitive questionnaire or loss of confidentiality. In addition, there may be discomforts or risks to you which are presently not foreseeable.

Benefits - You should not expect to gain any direct benefit from taking part in this study. We hope the establishment of this research registry will benefit other patients in the future by helping us learn about the various medical conditions from the future research you may participate in.

F. What about confidentiality of my "identifiable" information?

What information about me will be used for the research study?

The research team will share information among themselves as part of the research study process. In addition, various institutional committees and governmental agencies that oversee research may request or require access to your identifiable information. These include one or more Institutional Review Boards of CSMC, in an oversight capacity, the Cedars-Sinai Office for Research Compliance, the Food and Drug Administration, the Department of Health and Human Services, and other agencies that must receive reports about certain diseases. Also, other CSMC authorized researchers and authorized research assistants may receive information about you for future and related research purposes.

Why would my information be shared as part of the study?

Research involves the gathering and analysis of information. This protocol is designed to create a registry of women who are interested in contributing to research. We will use the information you provide to determine your eligibility for future research studies. Your identifiable information will only be shared with other researchers investigating diseases or conditions that may impact women. When a CSMC researcher presents the registry with a protocol (research study), the database will be searched using the inclusion/exclusion criteria mandated by the protocol. Any matches resulting from the database search will then be matched with the participant's name and address. You will then be contacted by the registry and provided information about the protocol. If you are interested in learning more about the protocol and authorize the registry to provide your name and address to the researcher, the registry will forward your information to the researcher. You may also utilize this opportunity to inform the registry if you are no longer interested in being a research registry member. You may decide to withdraw from the study at any time.

It is important for you to know that, if your information is used for teaching purposes outside the study, or to prepare a medical journal report about the research study, your identifiable information will not be made public; your identity will be kept confidential in those circumstances.

Each time your identifiable information is disclosed to any of the individuals listed above, precautions will be taken to minimize the possibility that the information shared could directly identify you. When possible, all identifying information will be coded. This means that the researchers will assign a unique code to represent your identifiable data so that people who see the coded data will not be able to identify you. You may choose not to participate in this study and, therefore, not authorize disclosure of your private information to the entities listed above.

You are being asked to authorize the research team to use and disclose your identifiable information indefinitely.

Under subpoena, CSMC may be bound by law to disclose your identifiable information. We will do everything we can to keep others from learning about your participation in the research. To further help us protect your privacy, we have applied for/received a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). A Certificate of Confidentiality will protect the investigators from being forced, even under a court order or subpoena, to release information that could identify you. We may release identifying information in some circumstances, however. For example, we may disclose medical information in cases of medical necessity, or take steps (including notifying authorities) to protect you or someone else from serious harm, including child abuse. This Certificate does not imply that the DHHS approves or disapproves of the project.

While the Certificate protects against forced disclosures, CSMC institutional policy requires that all research personnel comply with mandatory reporting requirements of the State of California. Researchers at CSMC must act upon and possibly disclose information about the possible abuse of or harm to a child, dependent adult, elder, yourself or another person, even if a Certificate of Confidentiality is in place. If the research team receives this type of information, the research team will need to take measures to protect the appropriate individuals from further abuse or harm.

G. What are my rights as a human research participant?

Taking part in this study is voluntary. You may choose not to take part or may leave the registry at any time. Your decision not to participate or to withdraw from the registry will not change your ability to receive clinical treatment and services at CSMC that are not related to this research. If you leave the registry, you will no longer be contacted by this registry about other research studies that you may be eligible for.

We will stop collecting any additional identifiable information about you. However, we are allowed by law to continue to use the information we already have about you, as necessary to maintain the integrity of the research study and make reports that oversight agencies require of us.

H. Whom do I call if I have questions or problems?

For questions about the study, contact C. Noel Bairey Merz, MD at (310) 423-9680. After hours and on weekends, call C. Noel Bairey Merz, MD at (310) 423-9662. For questions about your rights as a research participant, contact the CSMC Institutional Review Board (CSMC-IRB) office at (310) 423-3783. The IRB is a group of people who review the research to protect your rights and welfare.

