

**SUPPLEMENTAL CONSENT FOR
USE OF STORED SPECIMENS BY RESEARCHERS AT PRIVATE OR NON-PROFIT
ORGANIZATIONS**

THE WOMEN'S HEALTH INITIATIVE (WHI)

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Study Sponsor: National Heart, Lung, and Blood Institute (NHLBI)

1. Introduction

When you joined the study, you and all participants in the Women's Health Initiative were asked to sign a consent allowing research on your stored blood samples by WHI researchers. That research includes studies of genetic (inherited or DNA) differences that may affect disease or disease outcome. Much has already been learned from this research, and the blood samples provided by WHI women continue to be a very valuable scientific resource. Because of its scientific value, research on the blood samples has been expanded so that even more can be learned.

Up until now, all research on your samples has been done by WHI researchers and their colleagues at academic institutions. Every use of your samples is reviewed by study committees, by the NHLBI, and by an independent Institutional Review Board (IRB). An IRB is a board of experts at the research institution that carefully reviews proposed studies to make sure they do not violate the rights or safety of study participants. When you joined the study, you signed a consent allowing use of your samples. **The use of your samples by WHI researchers can continue under your existing consent. However, you are free to withdraw your existing consent at any time.**

Since the time WHI started, there have been many advances in the ways in which DNA and proteins in the blood can be studied. These new ways are now beginning to be used for predicting risk of diseases such as cancer and heart disease. Some of these new ways of studying DNA and proteins can only be done by private or non-profit organizations, because they have some of the most advanced technologies. **We are asking your permission to allow your DNA and blood samples to be shared with researchers at private (including for-profit companies) or non-profit organizations when that is the best way to advance scientific knowledge and public health. This consent would supplement (be in addition to) your existing consent for use of your samples by WHI researchers.**

2. Purpose of genetic and blood studies

Genetic (inheritance or DNA) studies look at DNA in blood cells to find genes that may cause or protect people from the health conditions affecting older women, e.g., heart disease, stroke, dementia, blood clots, cancers, fractures, and diabetes. Also, new ways of studying proteins in the blood are

being developed to find patterns linked to health conditions in older women. Other health conditions affecting women, beyond those currently considered in WHI, may be studied in the future as we gain new knowledge.

3. What am I being asked to do?

You are being asked to allow your genetic and blood samples to be shared with researchers at private or non-profit organizations. Your samples have already been collected and stored, so you will not be asked to give new blood or tissue samples. From the samples you have already provided, your white blood cells were obtained and frozen. The white blood cells are not alive and cannot be reproduced. In genetic studies, DNA is extracted from the white blood cells and differences in health conditions are examined. In the future, the DNA samples may be copied to produce DNA samples for the types of studies discussed above. Your DNA cannot be used for cloning.

If you agree, researchers at WHI or NHLBI may work with scientists in private for-profit and non-profit organizations in the future. There is value in bringing together scientists at WHI and NHLBI with other scientists who have special knowledge or skills. We believe working together makes the best possible use of the samples you have given. Working with scientists at private for-profit or non-profit organizations may lead to the development of new tests to diagnose or predict disease. It may also lead to the development of new medicines. The scientists from outside organizations will be given the blood or DNA only after the NHLBI and the Institutional Review Board have carefully reviewed their research proposals, and only after your name and all identifying information have been removed.

4. Are there risks from agreeing to the sharing of my samples?

All results in the WHI will be kept confidential and no results of genetic or blood studies done on your samples will be provided to you, your family, or your doctor. You will not be able to retrieve your samples or information about them. The genetic studies done in this study are for research only. The results of research studies like WHI apply to groups as a whole and we will not know what they mean for your personal health.

Participation in a genetic study does not mean that you have had genetic testing. Genetic testing means having a specific type of test performed and the results provided to you and your doctor. If you are interested in having genetic testing performed, you should consult your healthcare provider.

5. Will I get anything from the sharing of my samples?

You will not benefit directly from these genetic and blood studies. These studies may, one day, result in new tests and treatments or may help to prevent or cure disease. Scientific knowledge often advances slowly, but it may benefit future generations. Neither you nor your heirs will benefit financially from studies of these samples. Neither your blood nor DNA will be sold to anyone. The WHI program and the NHLBI will not profit from these studies.

6. Will this cost me anything?

There are no costs to you or your insurance carrier for any of the blood or genetic research studies.

7. What will happen to my samples?

Blood, urine, genetic samples, tissue samples, and/or other materials taken from you will be considered donated by you to medical research and will be under the control of the NHLBI. The WHI Clinical Coordinating Center provides these samples to NHLBI without personal identifying information, such as your name, address, or Social Security number. The WHI or NHLBI may share

your data and samples with other scientists who meet their requirements. All research on your samples will be done only by individuals and organizations that meet NHLBI standards and procedures. This means that research proposals will undergo careful review by WHI and NHLBI, or by an NHLBI review group, and by Institutional Review Boards. Organizations will be required to treat the data or samples as strictly confidential, and agree not to share data or samples with other parties.

Your blood and DNA samples will be stored at a central site listed under a code number. The samples will be stored for as long as they are useful for research. Your DNA may be copied, so that an unlimited supply can be available for future use without the need to obtain more blood from you.

By signing this consent form, your DNA and blood may be used by private for-profit or non-profit organizations for research. Researchers may only use the blood for the specifically approved purpose. They may not keep any leftover samples for other purposes. They must either return any unused remaining sample to NHLBI or dispose of the sample if so instructed by NHLBI.

8. How can I be assured that my results will be kept confidential?

All information collected during this research will be kept confidential and results will not be given to anyone without your permission, except as described below. Data may be given to other researchers for scientific purposes, but only after removing your name and all other personal identifiers. To ensure confidentiality, a study code number has been assigned to you. Samples provided to laboratories are labeled with a different code number. Only a small number of scientists and staff at the WHI Clinical Coordinating Center at the Fred Hutchinson Cancer Research Center will be able to link the study code number with the laboratory code number. The link will be kept in a secure location.

Your study records may be reviewed by authorized representatives from the National Heart, Lung, and Blood Institute (NHLBI), the Food and Drug Administration (FDA), the Office of Human Research Protection (OHRP), and the Institutional Review Boards in charge of protecting research participants at the WHI Clinical Coordinating Center and your WHI Clinical Center. By signing this consent form, you agree to this access to your records for the current study and any further research that may be conducted in relation to it (even if you withdraw from WHI). Because of the need at times to release information to the authorized groups listed above, absolute confidentiality cannot be guaranteed.

Any publication or presentation of the data will not identify you by name or any other means. Your information will be grouped with that of all other persons taking part in the WHI and will only be used for statistical analysis to further medical knowledge. When results of this study are published or presented at medical or research meetings, only group findings will be presented.

U.S. FEDERAL CERTIFICATE OF CONFIDENTIALITY

WHI has been granted a Certificate of Confidentiality from the United States Federal Government to make sure that we can best protect your confidentiality. This certificate means that WHI researchers cannot be forced to tell anyone not connected with the study about your participation, without your written consent. The researchers will only release information if you request it.

9. What if I decide to withdraw my consent to share my samples with private or non-profit organizations?

Your agreement to share your samples is completely voluntary and you may withdraw your consent for the use of your blood samples and DNA at any time. This will not affect your participation in the other parts of WHI. If you decide later that you don't want your blood or DNA to be used for future research at private or non-profit organizations, you may notify any of the people listed at the top of this document. They will make every effort to stop any additional studies with your samples and to return your samples to WHI. However, in some cases where the samples have already been shared or your DNA has been copied, it may not be possible to stop ongoing studies.

10. What if I have questions about the study?

If you have any questions about the use of your samples, you may contact the study researchers listed above. If you have any questions about your rights as a research subject, you may contact (IRB, number).

STATEMENT OF CONSENT

I agree to the sharing of my DNA and blood samples with researchers at private or non-profit organizations. By signing this form, I confirm that I have read the preceding consent information (or it has been read to me) and that I understand the contents. I will be given a copy of this consent form to keep.

I understand that samples and information collected from me will be used for research purposes only. My name or other information that could identify my family or me will not be released.

My signature below means that I have VOLUNTARILY agreed to release my genetic (DNA) samples and blood, for research purposes, to researchers from private or non-profit organizations who wish to develop tests to diagnose medical conditions, medications, or therapies that could benefit many people. (Note: Neither you nor your heirs will benefit financially from this, and neither your DNA nor your blood will be sold to anyone for profit.)

I understand that by signing this form I am not waiving any legal rights I may have.

Participant's signature

Date

Printed name of participant

Signature of person obtaining consent

Date

Printed name of person obtaining consent