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Participant Name: _____ Date: ___ / ___ / ____ (MM DD YYYY)

Study ID: _____

Title of Study: Million Veteran Program (MVP): A Partnership with Veterans (CSPG002)

Principal Co-Investigators: J. Michael Gaziano, MD, MPH; John Concato, MD, MPH Facilities: Boston/West Haven

Local Site Investigator(s): _____

Facility: _____ _____

INTRODUCTION

You are invited to take part in a research program that is funded by the Department of Veterans Affairs. Before you decide to take part, it is important to know why this research is being done and what it will involve including any potential risks to you as well as any potential benefits you may receive.

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the MVP staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you decide to take part, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the MVP staff.

BACKGROUND AND PURPOSE

Inherited traits are passed down from one generation to the next through genes. Genes are made up of DNA. DNA contains the information for the structure and function of our bodies. Most human diseases have an inherited, or genetic, element. Genes may also affect how we respond to certain treatments. Studying our genes can help us understand why some people respond to a treatment while others do not. Differences in genes may even explain why some people have bad reactions to certain medicines while others do not.

Scientists can now study the changes in genes and how such changes may affect risk for developing a disease or response to treatments. To help answer these questions, scientists will need to look at the genes as well as health and disease characteristics in very large numbers of people with and without a certain disease. Results from such research can help identify people with increased risk for specific diseases and allow for prevention or early treatment, where possible. This research can also lead to improved treatment by (1) prescribing the right medicine to people who will respond, and (2) reducing serious side effects. In addition, learning how genes cause disease can lead to the development of new treatments.

As part of the VA Genomic Medicine Program, VA researchers are conducting genetic and health studies for diseases/conditions that affect Veterans, with the ultimate goal of improving Veterans healthcare. The Million Veteran Program (MVP) is a national research program to learn how genes,

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lifestyle, and military exposures affect health and illness. All Veterans who are enrolled in the VA Healthcare System are eligible to participate. Findings from MVP may lead to better prevention and treatment of illnesses commonly seen in Veterans. Blood samples collected from patients and healthy individuals will be stored at the VA Central Biorepository. Information collected about Veterans health, disease characteristics and lifestyle will be stored in the VA Central Research Database. The goal is to make this chance to participate available to as many Veterans as possible and to follow and update their healthinformation over the years. We would like to enroll as many as 1 million Veterans nationwide over the next 5-7 years.

DURATION OF THE RESEARCH

Your personal time involved with this research is only the time it takes you to donate your samples and complete the surveys. You will be asked to donate sample(s) only once at the time you enroll in this program. However, if your sample is damaged or there is not enough for testing, we may ask if you would donate another sample. The sample you donate will remain in the VA Central Biorepository indefinitely. Also, we will use information from your medical record for as long as you are alive. This does not involve any personal time on your part, but you are being made aware that this study involves collection of information from your medical record for as long as you are alive unless the study closes for some reason or you withdraw your participation.

You will be sent newsletters at approximately yearly intervals. The newsletters will include contact information in case you have questions (for example, how to withdraw from the program). In addition, you may receive surveys for obtaining updated information not more often than once a year. A pre-addressed postage-paid envelope will be provided, should you choose to complete the surveys and return them.

STUDY PROCEDURES

Samples

We are asking permission to collect a blood sample from you. The sample will be used for future studies related to characteristics of health, or any disease, illness, or condition. DNA and/or other molecules derived from your sample will be used in these studies. We will ask you to donate a sample one time. However, if your sample is damaged or is not enough for testing, we may contact you again and ask that you donate another sample.

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We will collect about 2 teaspoons of blood from a vein in your arm. This blood sample will be labeled with a study code that does not contain your name, initials, date of birth, Social Security Number, or any other information that could identify you directly. The blood will be stored at the VA Central Biorepository until it is used up or until it is no longer of scientific value, at which time it will be destroyed.

Please note that if you are joining MVP at the same time you enroll in another VA study for which you are donating blood and we have determined that there will be enough for both studies, we will not ask you for a second blood sample.

Surveys

Completion of the short Baseline Survey is required for participation in MVP, and takes about 15 minutes to complete. You will also be asked to complete an optional second longer survey called the Lifestyle Survey. It has more detailed questions about your exercise habits, mental health, environmental exposures, and dietary habits and takes about 30-45 minutes to complete. You will be provided with a pre-addressed postage-paid envelope for returning the survey.

All surveys will be labeled with your a study code instead of your name to maintain confidentiality.

Please note that if you are joining MVP at the same time you enroll in another VA study for which you are completing the Baseline Survey, we will not ask you to complete it again for MVP. A copy of the Baseline Survey will be obtained from the other VA study you are enrolling in.

Medical and Research Records Access

If you agree to be in the program, we will obtain information from your medical records on an ongoing basis and add that information to the VA Central Research Database so that we can follow your health and care for as long as you are alive. A description of how your information is kept secure is discussed in the CONFIDENTIALITY section. If you participate or have participated in any other VA studies, we are asking your permission to access data from these studies and add that data to the VA Central Research Database.

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Use of Your Samples and Information
Your samples and/or medical information will be available to researchers at the VA, other Federal health agencies, and academic institutions within the United States for research projects approved by appropriate VA oversight committees. Approved research projects may be conducted at the VA, other Federal health agencies, or academic institutions within the United States. Your samples and medical information will only be provided to researchers in a coded manner so that they will not be able to identify you.

Future Contact
You may be contacted again in the future to determine your interest in participating in additional research. Potential research may include phone calls, surveys, in-person visits and/or providing another specimen. Your decision to participate in additional research is entirely voluntary. If you are interested, you will be asked to provide additional consent at that time.

POSSIBLE RISKS OR DISCOMFORTS
Any procedure has possible risks. The procedures you will undergo as part of MVP may cause all, some, or none of the risks and side effects listed. Rare, unknown, or unanticipated risks may also occur.

The risks of having blood taken from a vein in your arm are pain, bleeding, bruising, and rarely, infection at the site where the needle is inserted. Fainting or light-headedness may occur, but they seldom happen. If you are injured as a result of having blood drawn, VA will provide medical treatment for your research-related injury at no cost to you.

Filling out the surveys may result in distress if you are to find out about family health conditions of which you may not have been aware. Please note that your family members will NOT be contacted.

In the future, when the research results are published, they may show that certain groups (for example, racial, ethnic, or men/women) have genes that are associated with increased risk of a disease. If this happens, you or others may learn that you are at increased risk of developing a disease or condition. You and your family members might find this distressing.

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There is a slight risk of a breach of security, and if information about you does leak out, VA will not be able to guarantee that it will be protected. However, we will make every effort to protect your confidentiality and to make sure that your identity does not become known. All electronic information will be stored in a secure manner per VA Information Security Policy, including a secret code (encrypted) so no one can read it without the code. All written information will be stored in a locked file cabinet. Only a few authorized VA staff will know your identity (Read more on this in the section below on CONFIDENTIALITY). If you are injured while actively participating in this program or become upset while filling out a survey, you should contact the MVP Information Center at 1-866-441-6075.

POTENTIAL BENEFITS

You will not directly benefit from this program. Your sample(s) including DNA and any other molecules derived from it, combined with your medical information, may help researchers understand characteristics of any disease, condition, or illness. This may result in better ways to prevent, detect, and treat illnesses.

CONFIDENTIALITY

Taking part in this program will involve collecting private health information about you. This information will be protected in the following ways:

- Your sample(s) including DNA and any other molecules derived from it, as well as your medical and other personal information will be labeled with a study code instead of your name or other information that could identify you directly.
- The key that links the study code to your identity will be kept at the VA. Only a few authorized VA employees will have access to that key.
- The research database containing information from your medical records, DNA, and the survey(s) will be stored in a secure manner per VA Information Security Policy. This includes storing electronic information using a secret code (encrypted) so that no one can read it without the code.

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Testing on your sample(s) including DNA (genetic tests) or other molecules derived from it will be done for research purposes only. Because the results have no clear meaning at this time, we will not report these genetic test results to you or your doctor. The genetic test results will not be placed in your electronic medical record.

Your information will be combined with information from other people taking part in the study. We will write about the combined information we have gathered. Any talks or papers about this study will not identify you.

We will not share your information or identify unless we have to by law. There are times when we may have to show your records to other people. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other program monitors may view or copy portions of records that identify you.

To further help protect your privacy, we have received a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except in situations as follows: in the unlikely event of an audit by the government agency that gave us this Certificate, we may have to reveal your name, but only to the agency's authorized representatives. This Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. It also does not prevent us from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The Certificate of Confidentiality is not an endorsement of this research by the Department of Health and Human Services or the NIH.

COSTS TO PARTICIPANTS AND PAYMENT

Costs to Participants

You will not be charged for any procedures that are a part of this program. For Veterans who are required to pay co-payments for medical care and services by VA, these co-payments will continue to apply for medical care and services provided by VA that are not part of this program.

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Payment Offered for Participation

You will not be paid to participate in this program. Your samples, as well as medical and other personal information, will be used for research only. They will not be sold.

However, use of your sample may lead to inventions or discoveries that could become the basis for new products or treatments. These inventions, discoveries, or products could become commercially valuable and be patented and licensed. Commercially available products could also be developed directly from your blood or DNA. However, VA has no plans to share with you any profits from these inventions, discoveries, or products.

MEDICAL TREATMENT AND COMPENSATION FOR INJURY

If you are injured as a result of your active participation in this program, VA will provide medical treatment for your research-related injury at no cost to you. If you are injured as a result of your active participation in this program or become upset while filling out the survey, please call the MVP Information Center at 1-866-441-6075.

You do not give up any of your legal rights and you do not release the VA from any liability by signing this form.

VOLUNTARY PARTICIPATION

Your choice about participation in this program is voluntary. You may choose not to take part, and you will not lose any of your health benefits. If you decide to take part, you can change your mind at any time. Either way, your choice will not affect your care.

You may leave the program at any time. However, authorization to use your information for research studies remains in effect unless you notify VA in writing that you want it to end.

To leave the program and end authorization for use of your information, you may sign and submit the "MVP Withdrawal Form (Revocation of Authorization for Release of Protected Health Information For Research Purposes and Sample Withdrawal)." The mailing address is on the withdrawal form.

If you leave the program and end your authorization, researchers can continue to use health information that has already been collected on you. No further health information will be collected after you end authorization.

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If you leave the program and end your authorization your sample(s) including DNA or any other molecules derived from it will be destroyed so that they cannot be used in future research and no further testing can be performed on them. However, de-identified samples (where the link to your identity has been removed) that have been sent to researchers at other Federal health agencies or academic institutions cannot be recalled.

PERSONS TO CONTACT

If you have questions about this research program, you should contact the **MVP Information Center at 1-866-441-6075.**

If you have questions about your rights as a program participant, or you want to make sure this is an approved VA project, you may contact the VA Central Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in MVP. You may call the VA Central IRB toll-free at 1-877-254-3130 if you have questions, complaints, or concerns about the program.

GENETIC RESEARCH

Federal laws and policies provide you with protection from discrimination by health insurance companies, group health plans, and most employers based on your genetic information. A new federal law, the Genetic Information Nondiscrimination Act (GINA), will generally protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information obtained from this research.
- Health insurance companies and group health plans may not use your genetic information obtained from this research when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information obtained from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

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AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

The purpose of the Million Veteran Program (MVP), the VA Central Biorepository, and how my DNA will be used and stored has been explained to me. I voluntarily consent to donating a sample and my personal health information to the VA for the research purposes described above. I also give the VA permission to continue to take information from my medical records and add it to the VA Central Research Database so that my health status can be followed over time.

If there are any medical problems or questions or if I think I have been injured by participating in MVP, I can call the appropriate contacts listed above in the PERSONS TO CONTACT section. I may ask questions about this research at any time, and I may withdraw from MVP any time without penalty. I will receive a copy of this consent after I sign it.

I agree to participate in this research study as has been explained in this document.

Participant's Name	Participant's Signature	MM / DD / YYYY
Name of person obtaining consent	Signature of person obtaining consent	MM / DD / YYYY

ONLY WHEN APPLICABLE:

Name of witness	Signature of witness	MM / DD / YYYY

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