INTRODUCTION
You are invited to take part in research that is funded by the Department of Veterans Affairs. Before you decide to take part, it is important for you to know why this research is being done and what it will involve. This includes 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 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 contained, and that you were able to discuss any questions and concerns you had with MVP staff.

BACKGROUND AND PURPOSE
Genes are made of "DNA" that we inherit from our parents, making us who we are. For example, eye color, hair color, height, and some diseases are determined by our DNA. We are also learning that lifestyle factors, such as the food we eat and what we are exposed to in our environments (for example, chemicals during military service) can change our DNA and play a role in health and disease. But not everyone is affected the same. To find out why, we want to gather information from as many people as possible.

Results from such research may help identify people with increased risk for specific diseases and allow for prevention or early treatment. This research can also lead to improved treatment by prescribing the right medicine to people, and reducing serious side effects. In addition, learning how genes cause disease can lead to the development of new treatments.

The Million Veteran Program (MVP): A Partnership with Veterans is a national research program to learn how genes, lifestyle, and military exposures affect health and illness with the primary goal of improving health for Veterans and, ultimately, everyone. All Veterans are eligible to participate. The goal is to make MVP available to as many Veterans as possible and to follow and update their health information over time. We would like to enroll at least 1 million Veterans.

MVP PROCEDURES
If you agree to enroll in MVP, it takes just a few steps:

- Review, have your questions answered, and sign the informed consent and HIPAA authorization forms.
- Give 1 tube (about 2 teaspoons) of blood labeled with a code.
**Department of Veterans Affairs**

**VA RESEARCH CONSENT FORM**

Version Date: 01 / 07 / 2019

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<th>Participant Name: ___________________________</th>
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**Title of Research:** Million Veteran Program (MVP): A Partnership with Veterans (MVP 000)

**Principal Investigator:** J. Michael Gaziano, M.D., M.P.H.  
**Facility:** Boston

**Local Site Investigator(s):**

**Facility:** [ ] [ ] [ ] [ ] [ ]

- Allow permission to access your health records (VA and non-VA) on an ongoing basis.
- Complete the MVP Baseline Survey so we can understand more about you (this can be completed before or after you enroll).
- Agree to be contacted in the future.

**Once you are part of MVP:**

- We will store your information securely in the VA MVP Central Research Database.
- We will ask you to provide additional information (no more than once per year) about your health and lifestyle, starting with the MVP Lifestyle Survey.
- We may contact you about other (voluntary) research opportunities.
- We may contact you for additional permission to access your non-VA health records.
- We will process your blood sample to capture information about your genes (DNA) and other molecules. Your sample will be stored at the VA Central Biorepository indefinitely. Testing on your sample is done for research purposes only.
- We will not report results (including genetic) to you or your doctor, and results will not be placed in your health record. If there are medical advances or changes to the program that may require us to share certain results with you, we would contact you directly.
- We will add information from VA and non-VA databases, such as health and health-related records, or more general information such as where you have lived and served.

**DURATION OF THE RESEARCH**

Your personal time involved with this research is only the time it takes you to donate a blood sample and complete the surveys. You will be asked to donate blood once at the time you enroll in MVP. However, if your sample is damaged or there is not enough for testing, we may ask for another.

**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 drawn include pain, bleeding, bruising, and rarely, infection at the site where the needle is inserted. Fainting or light-headedness seldomly occur. If you are injured as a result of the blood draw, VA will provide medical treatment for your research-related injury at no cost to you.

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

When 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.

There may be a risk that genetic information obtained as a result of participation in research could be used to discriminate with regard to a person's health insurance or their job. However, as part of your participation in MVP, VA will not disclose your genetic information to health insurance companies, group health plans, or employers. In addition, researchers who will have access to your genetic information will take strict measures to maintain your confidentiality. In the rare event of a security breach, there are state, federal, and VA protections that prevent health insurance companies, group health plans, and most employers from discriminating against you based on your genetic information.

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. Read more on this in the section below on CONFIDENTIALITY.

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 personal health 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:
All MVP information will be stored securely in the VA MVP Central Research Database.

All samples will be stored in secure VA Biorepositories.

All samples and health information (VA and non-VA) will be coded (labeled in a way that does not directly identify you). Only select authorized MVP staff will have the ability to link the coded information to your identity.

Researchers who are approved access to analyze samples and data will not receive your name, date of birth, contact information, or social security number.

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

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, or local Research and Development Committee, and other program monitors may view or copy portions of records that identify you.

We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of MVP. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others. The Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in MVP.

COSTS TO PARTICIPANTS
You will not be charged for any procedures that are 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.

PAYMENT
You will not be paid to participate in this program. Your samples, as well as health 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 based on information 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 VA from any liability by signing this form.

**VOLUNTARY PARTICIPATION**

Your choice about participation in MVP 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 withdraw from MVP at any time. You may contact the MVP Information Center at 1-866-441-6075 or a local MVP office to withdraw or to learn more. You may also 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 HIPAA Authorization form.

If you withdraw from the program:

- 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 performed. However, coded samples that have already been sent to researchers cannot be recalled.

- 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.

**PERSONS TO CONTACT**

If you have questions about MVP please 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.
AGREEMENT TO PARTICIPATE IN THE RESEARCH PROGRAM

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, including non-VA health information, to VA for the research purposes described above. I also give VA permission to continue to take information from my health records and add it to the VA MVP 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 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.

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

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ONLY WHEN APPLICABLE:

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VA CENTRAL IRB APPROVAL STAMP

Jan 15 2019