

Research Consent Form (Blood Draw)

You are being asked to provide an additional blood sample as a current participant enrolled in MPCproject, a patient-partnered research project of Count Me In.

1. Why am I being asked to provide an additional blood sample?

An additional blood sample collection may help us to better understand how tumors, and patients' responses to treatments, may change over time.

2. What is involved if I agree to provide an additional blood sample?

We will ask you to have an additional sample of blood (2 teaspoons) drawn at your physician's office, local clinic, or nearby lab facility – we will provide detailed instructions on how to do this. We'll then ask you to send the sample to us in a pre-stamped package that we will provide.

3. Do I have to participate in this additional blood draw?

No. Providing an additional blood sample is voluntary.

4. Will I benefit from providing additional blood samples?

While providing additional blood samples will not improve your own health, the information we collect from these samples may aid in our research efforts to provide better cancer treatment and prevention options to future patients. We will provide updates about key research discoveries made possible by your participation on our website and/or through email.

5. What are the risks of providing an additional blood sample?

You may experience slight pain and swelling at the site of the blood draw. These reactions are rare and should get better within a few days. If they do not, you should contact your doctor. There may be a risk that your information (which includes your genetic information) could be seen by unauthorized individuals. However, we have procedures and security measures in place designed to minimize this risk and protect the confidentiality of your information.

6. Will it cost me anything to provide an additional blood sample?

No.

7. Who will use my blood samples?

Your samples will be available to researchers at the Broad Institute of MIT and Harvard, a not-for-profit biomedical research institute. After removing your name and other readily identifiable information, we may share research results obtained from your blood samples with the greater research community as well as central data banks at the National Institutes of Health.

In some cases, a research doctor may contact you to find out if you would be interested in participating in a different or future research study based on information that may have been found in your blood samples.

To allow sharing of information with other researchers, the National Institutes of Health (NIH) and other organizations have developed central data (information) banks that analyze information and collect the results of certain types of genetic studies. These central banks will store your genetic and medical information and provide the information to qualified researchers to do more studies. We will also store your genetic and medical information at the Broad Institute of MIT and Harvard and share your information with other qualified researchers. Therefore, we are asking your permission to share your results with these special banks and other researchers, and have your information used for future research studies, including studies that have not yet been designed, studies involving diseases other than cancer, and/or studies that may be for commercial purposes (such as the development or approval of new drugs). Your information will be sent to central banks and other researchers only with a code number attached. Your name, social security number, and other information that could readily identify you will not be shared with central banks or other researchers. We will never sell your readily identifiable information to anyone under any circumstances.

8. Will I be paid to take part in this research study?

No, you will not be paid for providing an additional blood sample.

9. What other options are there?

Providing an additional blood sample is voluntary – you may choose not to participate. Your decision not to participate will not affect your medical care in any way or result in any penalty or loss of benefits. It will also not affect the participation you have already agreed to for this research study.

10. Can I stop taking part in this research study?

Yes, you can stop being in the research study at any time. We will not be able to withdraw all the information that has already been used for research. If you tell us that you want to stop being in the study, we will destroy any remaining blood or DNA samples we have. We will not perform any additional tests on the samples. However, we will keep the results from the tests we did before you stopped being in the study. We will not be able to take back the information that already has been used or shared with other researchers, central data banks, or that has been used to carry out related activities such as oversight, or that is needed to ensure quality of the study.

To withdraw your permission, please contact the research doctor or study staff listed below by emailing info@mpcproject.org or calling 651-293-5029:

- Diane Diehl, PhD (Principal Investigator of the Study)

If you choose to not participate, or if you are not eligible to participate, or if you withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

11. What about confidentiality?

We will take rigorous measures to protect the confidentiality and security of all your information, but we are unable to guarantee complete confidentiality. When we receive your blood samples, your name and other information that could be used to readily identify you will be removed and replaced by a code. If we send your samples to our collaborators for gene testing, the samples will be identified using only this code. We will store your samples and information in locked facilities and in password-protected computer files at the Broad Institute and we will limit access to such files.

We may share your identifiable information or coded information, as necessary, with regulatory or oversight authorities (such as the Office for Human Research Protections), ethics committees reviewing the conduct of the study, or as otherwise required by law.

When we send the results of the gene tests and your medical information to central data banks or other researchers, they will not contain your name, social security number, or other information that could be used to readily identify you. The results of this research study or future research studies using the information from this study may be published in research papers or included in presentations that will become part of the scientific literature. You will not be identified in publications or presentations.

11. What if I have questions?

If you have any questions, please send an email to [project email address] or call [project phone number] and ask to speak with one of the project managers about this study.

For questions about your rights as a patient, please contact a representative of the Office for Human Research Studies at (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study. Please keep a copy of this document in case you want to read it again.

Documentation of Consent

This is what I agree to:

- ☐ You can work with me to arrange a sample of blood to be drawn at my physician's office, local clinic, or nearby lab facility.
- ☐ You can perform (or collaborate with others to perform) gene tests on the blood sample that I will send you and store the sample until this research study is complete.
- ☐ You can request my medical records from my physicians and the hospitals and other places where I received and/or continue to receive my treatment and link results of the gene tests you perform on my blood samples with my medical information from my medical records.
- ☐ You can use the results of the gene tests and my medical information for future research studies, including studies that have not yet been designed, studies for diseases other than cancer, and/or studies that may be for commercial purposes.
- ☐ You can share the results of the gene tests and my medical information with central data banks (e.g., the NIH) and with other qualified researchers in a manner that does not include my name, social security number, or any other information that could be used to readily identify me, to be used by other qualified researchers to perform future research studies, including studies that have not yet been designed, studies for diseases other than cancer, and studies that may be for commercial purposes.