doctor only if it is associated with a risk to your health and there is something that doctors can do about it. We will not provide this information if there are no actions that doctors can take to reduce your health risks. Please read the Detailed Information Sheet if you'd like additional information about this important issue.

12. What is an Institutional Review Board (IRB)?

An IRB is a group of people, including doctors, nurses, pharmacists, scientists, ethicists, and community members, who ensure that research involving human participants is well-planned and ethical. The IRB protects the rights and welfare of participants in research before and during the research study. DFCI has seven IRBs that review and oversee research.

13. Will it cost me anything to participate in this study? No.

14. What if I have questions?

If you have any questions, call 617-632-6008 and ask to speak with someone about the Cancer Research Study.

15. Will my private information be protected?

Federal law requires that DFCI and BWH protect the privacy of the information that identifies you. If you agree to participate in this study, you are authorizing the researchers at these institutions to access and use your private information. Because the research will be ongoing, your authorization will not expire unless you withdraw it in writing by contacting the Office of Human Research Studies, 450 Brookline Avenue, Boston, MA 02215.

This is what I agree to:

1. You can analyze my leftover specimens, link results to my medical information, and store specimens or material from them for possible future research use.

☐ Yes ☐ No

2. For most studies conducted under this protocol, a minimal amount of blood is sufficient. For these studies, you can take an extra tube of blood, a swab from my cheek, or a mouthwash and extra urine for analyses, and link the results to my medical information. You can store this material for possible future research use; and you can share the results of the analyses after you remove my personal identifying information.

☐ Yes ☐ No

3. You can tell my medical team what you find that might impact me and contact me in the future about other research studies that might be relevant to me.

☐ Yes ☐ No

4. Some other cancer research studies using this protocol may require more than one tube of blood. For these studies, you may withdraw up to four additional tubes of blood during a needle stick that you perform as part of my clinical care at this visit and/or future visits.

☐ Yes ☐ No

_____
Print Name

_____
Signature

Date of Birth _____

Medical Record # _____

Today's Date _____

Disease Center _____

☐ New Patient ☐ Existing Patient

If you are a patient with a blood-borne cancer, such as leukemia, lymphoma, or multiple myeloma, or you have a non-cancerous primary blood disorder:

More important information can be learned from your disease if additional blood and bone marrow can be obtained each time you have a blood draw or bone marrow examination. Only one additional tube of bone marrow would be obtained during your bone marrow needle stick.

As a patient with a blood-borne cancer or a non-cancerous primary blood disorder, this is what I agree to:

5. You may withdraw an additional tube of bone marrow during the bone marrow needle stick you are performing as part of my clinical care.

☐ Yes ☐ No

_____
Print Name

_____
Signature

Today's Date _____

_____
Interpreter/witness signature (if applicable)

DANA-FARBER CANCER INSTITUTE

BRIGHAM AND WOMEN'S HOSPITAL

Cancer Research Study

Researchers at Dana-Farber Cancer Institute (DFCI) and Brigham and Women's Hospital (BWH) want to learn as much as possible about the causes of cancers, leukemias, and other diseases, and to find new ways to treat them.

1. What is a research study?

A research study is an effort to learn more about a problem or to answer questions.

2. What is the purpose of this study?

Its purpose is to analyze some of your tissues and fluids and link that information with your clinical health information.

3. Why am I being asked to participate?

You are being asked to participate because:

- You have or have had cancer; or
- You are thought to have an increased risk for developing cancer; or
- You have a blood disease that is not cancer; or
- You have a disease that can be treated with bone marrow transplantation; or
- You are planning to donate bone marrow for transplantation

4. Do I have to participate in this study?

No. Taking part in this study is voluntary. Your care at DFCI or BWH will not be affected if you choose not to participate. Even if you decide to participate, you can change your mind and leave the study at any time. If you choose not to participate, or decide to participate and then later withdraw, you will not suffer any penalty or lose any benefits to which you are otherwise entitled.

5. Will I benefit from participating?

While taking part in this study may not improve your own health, we hope that the information we collect will aid in our research efforts to provide better cancer treatment and prevention options to future patients.

6. Will I learn the results of this study?

In general, we do not plan to contact you about the results of this study. However, a small number of the analyses we perform may have clinical importance. For example, they might uncover characteristics known to make cancers or hematologic diseases responsive to specific therapies. In addition, some of the analyses that currently have no clinical importance may later be discovered to have some.

Therefore, we are asking you to consider whether or not you would like us to inform your doctor about the results of these molecular analyses and to contact you in the future about additional research studies that may be appropriate for you.

7. What does this research study involve?

The samples we will analyze are comprised of cells. Within cells are genes. Genes contain the instructions which tell our bodies how to grow and work, and determine physical characteristics such as hair and eye color. Genes are composed of DNA. The order of DNA letters within genes spell out these instructions. We plan to do research on how genes influence the behavior of cancers. We also plan to do non-genetic tests that are relevant to your disease.

This will be done by performing analyses on your tissues (obtained during your routine biopsies or surgery), blood, or other body fluids, such as saliva or urine. Importantly, we will use tissue specimens that have already been collected and stored as part of your clinical care. Analyses will be performed on material only after all necessary clinical tests have been performed. However, we are asking your permission to obtain one additional sample of blood (a few teaspoons) and a swab from the inside of your mouth or a mouthwash to obtain some cells. These are sources of non-cancer cells which are needed for some types of analyses. You may provide additional blood samples (up to 4 tubes, or approximately 2 tablespoons each) if you so choose. Patients with leukemia or lymphoma (hematologic malignancies) or non-cancerous diseases of the blood may be asked to provide additional material (see other side of this brochure for details).

This study also asks your permission to link the results of these analyses with clinical information that has been generated during the course of your clinical care. This way, we can relate your gene results to your clinical situation.

Some of your specimens and the material generated during the analysis of your specimens may be useful for future study. We are asking your permission to store these specimens and materials in secure storage facilities (called “repositories” or “banks”) for possible later use.

8. What will I have to do if I agree to participate in this study?

Participation will require little extra effort on your part. The tissues we will analyze have been, or will be, obtained during your routine surgeries, biopsies, or other clinical procedures. Your only additional activities would be, if you agree, providing a tube of blood and a swab of the inside of your cheek or a mouthwash.

9. Are there risks to me if I participate in this study?

Blood drawing may cause some discomfort. There may also be a risk that your confidentiality may be breached. In addition, there is an increased risk of loss of privacy whenever genetic research is done, but again, there are procedures to minimize this risk. We have procedures and security measures in place to ensure that it will be extremely difficult for this to happen.

10. What types of research projects will the DFCI and BWH researchers do with my specimens and health information?

Examples of the studies that may be done include, but are not limited to:

- Studies that will help us understand how cancer forms within the body
- Studies that will examine whether certain genes or DNA sequences protect or predispose people to developing cancer
- Studies that will help with the development of new cancer drugs

Some of these studies may be published.

11. Who will use my samples and see my information?

Your specimens and health information will be available to researchers at the Dana-Farber/Harvard Cancer Center who have approval from the DFCI Institutional Review Board to use your samples and health information for research that is conducted under this Cancer Research Study. Your specimens may be shared with other places, such as the institutions that will conduct the sequencing. No information that could identify you will be sent with your specimens. In addition, if you agree, we will share your results with central data repositories (such as the National Institutes of Health), which may share information without your permission. Your name or other directly identifiable information would not be provided to these central repositories.

Test results will not be placed in your medical record. However, if you agree to let us tell your doctor about the results of these cancer-related tests, he or she may tell you about them and offer genetic counseling, if you wish to have it. It is possible that some tests will reveal non-cancer related information. If so, we will provide this information to your