such as ancestry, might be inferred from the results of this study. Proper assessment of this non-cancer information should be performed with the participation of a genetic counseling team and laboratory that specializes in the appropriate type of non-cancer genetic analysis. Also, some of the genetic information that will be reported today as "uncertain" in its importance might be found, in the future, to be important, either for cancer or for non-cancer related health conditions. Re-interpretation in the future may be performed upon request, but will not be performed automatically.

12. Will it cost me anything to participate in this study?

No. However, you or your insurance company may be charged for portions of your care that are considered to be standard clinical care. You may be responsible for co-payments and deductibles that are typical for your insurance coverage.

13. 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.

14. 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 research 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 your authorization in writing by contacting the Office of Human Research Studies, 450 Brookline Ave., Boston, MA 02215.

The Detailed Information Sheet provides additional information about this research study. A copy will be provided to you.

This is what I agree to:

1. You can analyze my leftover specimens, link results to my medical information, and store specimens or materials from them for possible future research use. You can contact me about additional research studies that may be appropriate for me based on my Profile results. You can put results that might affect my medical care in my medical record. I understand that these results will stay in my record even if I withdraw from the study. Please note that you must agree to have Profile results placed in your medical record in order for Profile testing to be performed.

☐ 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. I understand that there may be a small risk that my results could be used to identify me.

☐ Yes ☐ No

3. 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

4. *Hematologic Malignancy patients only (i.e., patients with a blood-borne cancer, such as leukemia, lymphoma, or multiple myeloma, or a non-cancerous primary blood disorder)*

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

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

☐ **Participant has received a copy of the Detailed Information Sheet**

_____

Print Name

_____

Signature

_____

Date of Birth

Medical Record # _____

Today's Date _____

Disease Center _____

☐ New Patient ☐ Existing Patient

_____

Interpreter/witness signature (if applicable)

DANA-FARBER CANCER INSTITUTE

BWH 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. However, if you do agree to participate, some of your testing results, including Profile testing, will be placed in your medical record. Those results will remain in your medical record even if you withdraw from the study.

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 for future patients.

6. Will I learn the results of this study?

Most often, the results of research studies do not have any effect on clinical care. However, some of the test results from this study could be important for your clinical care. If you agree to participate in this study, these results will be put in your medical record so that your health care provider and you can use them for your medical management.

In addition, some of the research results that currently do not impact your clinical care may be found to be clinically important later. Some results may also qualify you for additional research studies such as clinical trials of new drugs.

7. What does this research study involve?

The samples we will analyze are comprised of cells. Within cells are genes. Genes contain the instructions that 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 some 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.

For patients with hematologic malignancies (blood cancers) or non-cancerous blood diseases, 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.

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 materials 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 tubes 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?

Drawing blood may cause some discomfort. There may also be a risk that your confidentiality may be breached. In addition, there is an increased risk of privacy loss 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;
- Examine whether certain genes or DNA sequences protect or predispose people to developing cancer;
- 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 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 and others), which may share information without your permission. Your name or other directly identifiable information would not be provided to these central repositories. Despite removing this information, there is a small risk that someone could use these results to identify you if they have another source of genetic material that could be matched to your specimen. We work with the entities we share your data with to make this risk as small as possible.

Based on the results of tests, your health care providers may discuss your results and offer genetic counseling if you wish to have it. This study is not designed to analyze genetic information that is unrelated to cancer or inherited cancer risk. However, some additional non-cancer information,