1. What is the purpose of this study?

You are being asked to participate in a research study to help doctors and scientists understand why cancer occurs and to develop ways to better treat and prevent it. You are being asked to participate because you have cancer now or you are at risk of developing cancer.

Its purpose is to analyze some of your tissues and fluids and link that information with your clinical health information. The tests being performed on your tissues or fluids are designed to look for changes that might be associated with cancer.

2. Why am I being asked to participate?

You are being asked to participate because you have been diagnosed with an early phase of a blood cancer, also known as precursor condition.

3. 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.

4. Will I benefit from participating?

It is important to understand that this is not a clinical study being done to benefit you directly. Therefore, taking part in this research study may not directly benefit you. However, the information gained from your participation is likely to generate important information which will help future patients with blood cancers and individuals at high risk of developing those diseases.

5. What does this research study involve?

You will not undergo tests or procedures that are not required as part of your routine clinical care. We will ask you to provide an additional sample from tissue that is obtained for your clinical care.

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 such as the effect of immune regulation on disease progression.

This will be done by performing analyses on your tissues (obtained during your routine lymph node or bone marrow biopsies), 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 or bone marrow (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 2 tubes, or approximately 2 tablespoons each) if you so choose. Only one additional tube of bone marrow would be obtained during your bone marrow needle stick.

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

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 during your current visit.

You will also be asked to follow up with your doctor at regular intervals (e.g., every 6 months or every year) to make sure that you are followed for the potential of clinical progression of your cancer. During these visits, if you agree, an additional tube of blood or sample of your bone marrow or biopsy of your lymph nodes or other tissue will be obtained, as well as, you may be asked to provide a urine sample.

If you cannot come to our Institute, then we ask you to follow up with your local doctor at the same intervals to assess your clinical course. We ask your permission to contact your doctor to obtain information about your clinical course and whether there is progression of your disease.

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

There are small risks associated with obtaining the additional tube of blood, bone marrow and the swab from the inside of your cheek. In addition, it is also possible that the analyses and/or results, including the identification of genetic abnormalities in you or your cancer, could be seen by unauthorized individuals. We have tried to minimize this risk by imposing rigorous controls on access to the computers that would house your information.

8. What types of research projects will 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.

9. 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 may 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.

10. Can I stop being on the research study and what are my rights?

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this research study. You can stop being in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Any samples of yours that were anonymized (identifying information removed) will not be discarded. Leaving the research study

will not affect your medical care outside of the research study.

11. Will it cost me anything to participate?
There will be no additional costs to you for participating in this study.

12. What if I have questions?
If you have any questions, call 617-582-8664 or email precursor@partners.org.

13. Will my private information be protected?
We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

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.

The results of this research study may be published. You will not be identified in publications without your permission.

Please read the Detailed Information Sheet if you would like additional information about this research study.

This is what I agree to:

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

❑ I agree
❑ I do NOT agree

2. You can take an extra tube of blood, bone marrow, tissue biopsy, or a swab from my cheek or a mouthwash and extra urine for analyses, as needed during scheduled visits to my doctor, 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 agree
❑ I do NOT agree

3. During my participation in this study, if I am unable to return to DFCI, you can contact my local doctor to access my medical records and leftover specimens.

❑ I agree
❑ I do NOT agree

4. You can contact me in the future about other research studies that might be relevant to me.

❑ I agree
❑ I do NOT agree

_____
Print Name

_____
Signature of Participant or Legally Authorized Representative

_____
Relationship of Legally Authorized Representative to Participant

_____ _____
Today's Date Time (AM/PM)

_____ _____
Medical Record # Date of Birth

Center for Prevention of Progression of Blood Cancers

Study of Precursor Hematological Malignancies to Assess the Relationship between Molecular Events of Progression and Clinical Outcome