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CONSENT FORM

CIRB S9007: Cytogenetic Studies in Leukemia Patients

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SWOG-9007: Cytogenetic Studies in Leukemia Patients

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

You are being asked to take part in this study because you have acute leukemia, chronic leukemia, myelodysplastic syndrome (MDS), or myeloproliferative disorder (MPD).

Why is this study being done?

The purpose of this study, which is a companion protocol that goes along with leukemia clinical studies, is to identify and to examine genetic defects (identified in laboratory tests called cytogenetic studies) in leukemia and related disorders including myelodysplastic syndrome (MDS), and myeloproliferative disorder (MPD). The results from cytogenetic studies that are part of the routine first patient workup of patients with leukemia and related disorders will be used to study the medical importance of these abnormalities. The results from your cytogenetic study will be combined and compared to those from several other patients.

Information gained from such research may add to a greater understanding of the reasons for treatment failure and may help in the selection of appropriate treatment for individual patients.

How many people will take part in the study?

The number of people who take part in this study depends on the availability of treatment protocols.

What will happen if I take part in this research study?

As part of the standard procedure for initial evaluation of patients with leukemia and related disorders before any treatment, cytogenetic studies will be ordered by your physician on either a bone marrow or blood specimen, or both. Approximately 2 to 3 cc (less than 2 teaspoonfuls) of bone marrow and/or blood will be obtained.

Most of the time the diagnostic bone marrow sample and the bone marrow sample for cytogenetics can be drawn through the same needle and an extra needle puncture is usually not necessary.

Can I stop being in the study?

*(If patient is required to participate in **SWOG-9007** according to treatment study:)* You can decide to stop the treatment study at any time. If you do that, no more bone marrow or blood samples will be sent for research on this companion study. However, any bone marrow or blood samples that were already submitted may have already been used for research.

*(If patient is not required to participate in **SWOG-9007** according to treatment study:)* Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop.

What risks can I expect from being in the study?

The greatest risk to you is the release of information from your health records. We will do our best to make sure that your personal information will be kept private. The chance that this information will be given to someone else is very small.

The bone marrow aspiration may or may not cause discomfort or pain, but if pain does occur with the first bone marrow aspiration, the same pain will probably occur with the second aspiration for the research sample.

For more information about risks, ask your study doctor.

Are there benefits to taking part in the study?

The benefits of cytogenetics research include learning more about what causes cancer and other diseases, how to prevent them, and how to treat them.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Not participating in this companion study *(Institutions must delete this option if patient is required to participate in **SWOG-9007** according to treatment study.)*
- Not participating in this treatment study
- Taking part in another study

Talk to your doctor about your choices before you decide if you will take part in this study.

Will my medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. To help maintain your privacy, records containing your cytogenetic results will be coded using a number. Your name will not be used in the records. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The Southwest Oncology Group
- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), involved in keeping research safe for people, and the Cancer Trials Support Unit (CTSU), a research group sponsored by the NCI to provide greater access to clinical trials.

In the future, people who do research may need to know more about your health. While the Southwest Oncology Group may give them reports about your health, it will not give them your name, address, phone number, or any other information that will let the researchers know who you are.

What are the costs of taking part in this study?

As part of the standard procedure for evaluation of patients with leukemia and related disorders, a cytogenetic study will be ordered by your physician. Since this test is part of the standard clinical workup for patients with leukemia and is considered part of good clinical practice, you and/or your health plan/insurance company will be billed for the cost of the test. There is no cost to you for this research study. The gathering of the results of the cytogenetic test and the keeping of research records will be paid by those organizing and conducting the research.

You will not be paid for taking part in this study.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at <http://cancer.gov/clinicaltrials/understanding/insurance-coverage> . You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at the phone number on the cover sheet.

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. However, if you do not take part in this companion study, then you cannot take part in the treatment study. (*Institutions must delete this sentence if patient is not required by the treatment protocol to participate in **SWOG-9007**.*) No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your willingness to continue in the study.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor at the number listed on the cover sheet.

For questions about your rights while taking part in this study, call the *Northwest Community Clinical Oncology Program at 253-403-1461* or the Institutional Review Board (a group of people who review the research to protect your rights) at 253-403-3844.

*You may also call the Operations Office of the NCI Central Institutional Review Board (CIRB) at 888-657-3711 (from the continental US only).

Where can I get more information?

You may call the National Cancer Institute's Cancer Information Service at:
1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

You may also visit the NCI Web site at <http://cancer.gov/>

- For NCI's clinical trials information, go to: <http://cancer.gov/clinicaltrials/>
- For NCI's general information about cancer, go to <http://cancer.gov/cancerinfo/>

You will get a copy of this form. If you want more information about this study, ask your study doctor.

Signature

I have been given a copy of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I agree to take part in this study.

Patient's name (printed or typed)

Patient's Signature Date

Physician name (printed or typed)

Physician Signature Date

Signature of person conducting the
Informed consent discussion

Date

Authorization to Use or Disclose (Release) Identifiable Health Information For Research

Participant's Name: _____

Birthdate: _____

1. What is the purpose of this form?

The **Southwest Oncology Group** is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your health information for research. This information may include data that identifies you. Please carefully review the information below. If you agree that researchers can use your identifiable health information, you must sign and date this form to give them your permission.

2. What health information do the researchers want to use?

The researchers want to abstract and use the portions of your medical record that they will need for their research. If you enter a Southwest Oncology Group research study, information that will be used and/or released may include your complete medical record, and in particular, the following:

- the history and diagnosis of your disease
- specific information about treatments you received
- information about other medical conditions that may affect your treatment
- medical data, including laboratory test results, tumor measurements, CT scans, MRIs, X-rays, photographs of radiation therapy target areas, and pathology results
- information on side effects (adverse events) you may experience, and how these were treated
- long-term information about your general health status and the status of your disease
- tissue and/or blood samples, associated data related to the analysis of the samples

You may request a blank copy of the Southwest Oncology Group data forms from the Northwest CCOP to learn what information will be shared.

3. Why do the researchers want my health information?

The Northwest CCOP will collect your health information and share it with the Southwest Oncology Group if you enter a Cooperative Group research study, or to evaluate your eligibility for a study. The Southwest Oncology Group researchers will use your information for the following cancer research study(ies). You are being asked to take part in a study known as SWOG 9007: Cytogenetic studies in leukemia patients.

4. *Who will be able to use my health information?*

The Northwest CCOP will use your health information for research. As part of this research, they may give your information to the following Groups taking part in the research. The Northwest CCOP may also permit staff from these Groups to review your original records as required by law for audit purposes.

- the Southwest Oncology Group (SWOG)
- the Cancer Trials Support Unit (CTSU), a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials
- public health agencies and other government agencies (including non-U.S.) as authorized or required by law
- other people or organizations assisting with Southwest Oncology Group research efforts, (Aesgen, the manufacturer of glutamine) and the Food and Drug Administration
- central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your health information to those groups listed above.

5. *How will information about me be kept private?*

The Southwest Oncology Group will keep all identifiable health information confidential to the extent possible, even though they and other federal research groups are not subject to the same federal privacy laws governing clinical centers. The Southwest Oncology Group will not release identifiable health information about you to others except as authorized by this form, or required by law. If your identifiable health information must be shared with other organizations, the privacy laws that govern those organizations would apply.

6. *What happens if I do not sign this authorization form?*

If you do not sign this authorization form, you will not be able to take part in a research study for which you are being considered.

7. *If I sign this form, will I automatically be entered into the research study?*

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a separate research consent form.

8. *What happens if I want to withdraw my authorization?*

You can change your mind at any time and withdraw this authorization. This request for withdrawal must be made in writing. Beginning on the date you withdraw your authorization, no new identifiable health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your authorization, you will be removed from the research study at that time.

To withdraw your authorization, please contact the person below. She will make sure your written request to withdraw your authorization is processed correctly.

Karyn Hart, RHIT, CCRP
Clinical Research Associate
Northwest CCOP
315 Martin Luther King Jr, Way
Tacoma, WA 98405
(253) 403-1461

9. How long will this authorization last?

If you agree by signing this form that researchers can use your identifiable health information, this authorization has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding my identifiable health information?

You have the right to refuse to sign this authorization form. You have the right to review and/or copy records of your health information kept by the Northwest CCOP. You do not have the right to review and/or copy records kept by the Southwest Oncology Group or other researchers associated with the research study.

Signatures

I agree that my identifiable health information may be used and disclosed for research purposes described in this form.

Signature of Patient or Patient's Legal Representative: _____ Date: _____

Printed Name of Legal Representative (if any): _____

Representative's Authority to Act for Patient: _____

Signature of Person Obtaining Authorization: _____

Printed Name of Person Obtaining Authorization: _____