Cost-Effectiveness Research

INFORMED CONSENT

Study Title: Ancillary Cost-Effectiveness Study to BMT CTN 1102

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Cost-Effectiveness Research (Optional)

This section of the consent form is about cost-effectiveness research that will look at how much you and your insurance pay for your treatment. The researchers want to understand how much different therapies cost. You may choose to let the researchers collect information on the cost of your treatment for this study if you want to.

You can still be a part of the main study (health evaluations by phone) even if you say 'no' to give information on the cost of your treatment.

Study purpose: The study doctors want to learn more about the costs of the two types of treatments that are being compared in the main study: 1) transplant from a well matched family donor or unrelated donor; and, 2) blood transfusion and drug therapy only (no transplant).

This research will help doctors understand the cost-effectiveness of these treatments. In particular, researchers want to know if costs are a problem for patients and their families. They also want to know how out-of-pocket financial costs (costs not covered by your insurance) differ by treatment type and by type of insurance. This will help them understand cost barriers for patients with different treatments.

Lead study doctor: Scott Ramsey of the Fred Hutchinson Cancer Research Center in Seattle is the lead study doctor for the cost-effectiveness research. Dr. Ramsey is a medical doctor and well-known health economist who has studied costs of many different cancer treatments.

Your health insurance and out-of-pocket medical costs: If you agree to join this study, we will ask for the following information about your health insurance:

1) Type
2) Provider
3) Policy number
4) Group number
5) Policy holder's name and date of birth.

We will also want to know about your out-of-pocket costs. The out-of-pocket costs you and

your family have to cover are important in understanding the overall cost of medical care, so we want to collect this information as well. For example, we want to know how much you spend on:

1) Medical costs (for example, co-pays, prescriptions)

2) Travel and lodging

3) Cost of time away from work

Your health insurance and out-of-pocket information is called the 'study data' in this consent form.

How we will use your health insurance information: After you finish the study, we will use your insurance information to learn about the payments your health insurer made. We will calculate the cost of your medical care (both groups that are being compared, the transplant group and the no transplant group). Because treatment (either transplant or non-transplant therapies) can impact your health for many years after you join the study, we want to collect insurance payment information for the 12 months before you joined the study, and for 3 years after your treatment start date.

Privacy, confidentiality and use of information: Only the study doctors at the Fred Hutchinson Cancer Research Center (FHCRC) will have access to your health insurance information and out-of-pocket cost information (study data). The FHCRC will contract with the Survey Research Group (SRG) at the CIBMTR to collect out-of-pocket cost data, who are also administering the telephone health surveys as part of the parent study. To maintain your confidentiality, we will not link your name to the study data. Also, all of the study doctors signed a confidentiality agreement and promised to keep electronic data protected under passwords and physical data (paper or other media such as CDs) in secure facilities (for example, on-campus locked offices and locked filing cabinets).

Collecting the study data: We will collect your health insurance information at the time of study enrollment. Out-of-pocket cost data will be collected by mail-out survey. The mail-out surveys were designed to be very user friendly, but we will help you with the cost diary over the phone if needed. We will also place phone call reminders.

We will ask you about your out-of-pocket costs only 3 times during the course of the study: at 1, 7 and 19 months after enrollment. We think each questionnaire will take between 10 and 30 minutes to complete, but this depends on how much information there is to enter.

Alternate contact: We ask that you give us the name of an alternate contact. This may be your spouse, partner, parent, adult child or sibling, or friend. You may not feel like answering the questionnaires or need help gathering cost information, so we ask that this individual help with this information

Risks to participating: The risks to participating in the cost-effectiveness study are small. A possible risk is the loss of confidentiality about your medical information, but the chance that this

information will be given to someone else is very small.

Payment and costs: You will not get paid for participating in this study. You will not be charged for taking part in this study.

Right to ask questions and/or withdraw: You do not have to be part of the cost-effectiveness research study. Your participation is voluntary. If you decide not to be part of this study, it will not affect your regular medical care or services. You can quit the study at any time.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

For more information: Contact the Study Coordinator at the Fred Hutchinson Cancer Research Center at (844) 840-2731 or email: 1102-CEA@fredhutch.org

Making Your Choice

Please read each sentence below and think about your choice. After reading each sentence, please indicate your choice below. If you have any questions, please talk to your doctor or nurse, or call Karen Hansen, Director at the FHCRC research review board at: (206) 667-4867.

No matter what you decide to do, it will not affect your care.

Statement of Consent for Cost-Effectiveness Research Study (Optional)

The purpose of the cost effectiveness research, the procedures involved, and the risks and benefits have been explained to me. I have asked all the questions I have at this time and I have been told whom to contact if I have more questions. I have been told that I will be given a signed copy of this consent form to keep.

I understand that I do not have to participate in the cost effectiveness research. If I decide to not participate, it will not affect my medical care in any way.

❑ I agree to be part of the cost-effectiveness research.

❑ I do not agree to be part of the cost-effectiveness research.

Signature _____ Date _____

(Version date 1/30/15)

FRED HUTCHINSON CANCER RESEARCH CENTER
Institutional Review Board

HIPAA Authorization for the Use of Member Protected Health Information for Research

IR number: 9159 **Protocol number:** 1.0

Title of Research Study: *Ancillary Cost-Effectiveness Analysis to:* A Multi-Center Biologic Assignment Trial Comparing Reduced Intensity Allogeneic Hematopoietic Cell Transplant to Hypomethylating Therapy or Best Supportive Care in Patients Aged 50-75 with Intermediate-2 and High Risk Myelodysplastic Syndrome BMT CTN 1102

The research study named above and described more fully in the informed consent form that you sign ("Research Consent") requires that the researchers have access to health insurance information about you (also called "Protected Health Information" or "PHI"). By law, your health insurance provider (the "Insurer") must protect the confidentiality of your PHI. The researchers can obtain your PHI from the Insurer and use it for research **only if you authorize and direct the Insurer to share it with them.**.

This authorization form ("form") describes what types of PHI the researchers need and what they will do with it as part of the research study. Please read it carefully. If you agree with it, please sign your name at the bottom. You will be given a copy of this form after you have signed it.

If you sign this form, your PHI will be shared with Fred Hutchinson Cancer Research Center, its staff, and others who work with them. In this form, the term for all these people is "Researchers" and they are described more fully in the Research Consent. The Researchers will use the PHI only for the purposes described in the Research Consent and in this form.

1. The protected health information to be obtained and used by the Researchers for the Study includes:

- All health insurance information including the type of health insurance, provider, policy number, group number and the policy holder's name and date of birth. It also includes information about health care costs and health care claims information as well as reimbursements made by your health insurer(s).

- The specific protected health information that will be obtained from the Insurer and used for the Research is described below:

    - Dates and codes associated with medical service and diagnoses
    - Location of medical service
    - Provider of medical service

2. What the Researchers will do with your Protected Heath Information.

The Researchers will use your PHI only in the ways described in the Research Consent form that you sign and as described here. They may also share your PHI with certain people and groups. These may include:

- The sponsor of the Study, The National Heart, Lung and Blood Institute. The sponsor reviews the Study. Government agencies, review boards, and others who watch over the safety, effectiveness and conduct of the research

- Others, if the law requires.

By law, the Researchers are required to protect the confidentiality of your PHI. The Research Consent form you sign describes in more detail how your PHI will be protected. You may ask questions about what the Researchers will do with your information and how they will protect it. Privacy laws do not always require the receiver of your information to keep your information confidential. After your information is given to others, there is a risk that it could be shared without your permission.

You are free to refuse to allow the Researchers access to your PHI. If you refuse, you will not be able to participate in this research study but your refusal will not affect your health insurance eligibility or coverage.

3. How long the permission will last?

The permission for the Researchers to obtain and use your protected health information will end when the Researchers complete the research study AND any review of the research study is completed.

4. Canceling your permission.

You may change your mind and take back your permission anytime. To take back your permission, please send a written request to the research study coordinator, Lisel Koepl, at Fred Hutchinson Cancer Research Center, 1100 Fairview Ave North, M/S M3-B232, Seattle, Washington 98109-1074. If you do this, you may no longer be allowed to be in the research study. The Researchers may still keep and use any Protected Health Information they already have. But they can't obtain more PHI about you for the research study unless it is required by a federal agency that reviews the research.

5. Giving permission

You give your permission for the use of your protected health information by signing this form.

Signature

I authorize and direct the Insurer to provide access to my protected health information to the Researchers as described in this authorization form.

_____	_____
Signature of participant or participant's Legal Representative	Date
_____	_____
Printed name of participant or participant's Legal Representative	Representative's relationship to participant

Primary insurance (if any):

Health Insurer: _____ Type of Insurance: _____

Policy Number: _____ Group Number: _____

Policy Holder's Name: _____Policy Holder's Date of Birth: _____

Additional insurance (if any):

Health Insurer: _____ Type of Insurance: _____

Policy Number: _____ Group Number: _____

Policy Holder's Name: _____Policy Holder's Date of Birth: _____

If more than 2 insurance providers, please add additional insurance information below:

Health Insurer:_____ Type of Insurance: _____