Medical College of Wisconsin and Froedtert Hospital
CONSENT TO PARTICIPATE IN RESEARCH

Name of Study Subject: _____

PILOT STUDY USING PROPRANOLOL TO PROMOTE PRENYLATION OF THE GTPASE RAP1B IN HEMATOPOIETIC STEM CELL TRANSPLANT RECIPIENTS

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You are invited to take part in this research study. This form tells you why this research study is being done, what will happen in the research study, and possible risks and benefits to you. If there is anything you do not understand, please ask questions. Then you can decide if you want to join this study or not.

A1. INTRODUCTION – WHY ARE WE ASKING YOU ABOUT THIS STUDY?

You are invited to participate in this ancillary research study because you have multiple myeloma and will be participating in the main research study *A Randomized Controlled Pilot Study Using Propranolol to Decrease Gene Expression of Stress-Mediated Beta-Adrenergic Pathways in Hematopoietic Stem Cell Transplant Recipients.*

A total of about 40 people are expected to participate in this ancillary study all at the Medical College of Wisconsin.

The Director of the study is Jennifer Knight, MD in the Department of Psychiatry. A study team works with Dr. Knight. You can ask who these people are.

A2. DO I HAVE TO BE IN THIS STUDY?

You can decide whether to take part in this ancillary study or not. You are free to say yes or no. If you say no, your regular medical care will not change. Even if you join this study, you do not have to stay in it. You may stop at any time.

A3. WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this ancillary study is is to look at whether the drug (propranolol) affects Rap1 prenylation, which is one way that cancer cells can spread.

B1. WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

Baseline Visits

If you agree to participate in the main study you will be asked to:

- Sign this informed consent form
- You will have blood taken for research samples

Summary of Study Procedures:

Day -2 prior to your transplant (Both Groups of main study)

- You will have approximately 8 mL or 1 tablespoon of blood taken for research samples on approximately day -2 (2 days before your transplant)

Day 28 after your transplant

- You will have approximately 8 mL or 1 tablespoon of blood taken for research samples on approximately day 28 after your transplant.

B2. HOW LONG WILL I BE IN THE STUDY?

You will be in this research study until your last blood draw which is on approximately day 28 after your transplant.

B3. CAN I STOP BEING IN THE STUDY?

You may stop at any time. If you decide to leave the study, please let the study team know.

The study investigator may stop your participation in the study at any time for any reason without your consent. He / She will tell you if this happens.

C1. WHAT RISKS OR PROBLEMS CAN I EXPECT FROM THE STUDY?

Blood Samples:

The tests done at each visit are standard medical tests. The samples obtained for research purposes will be collected at the same time that you are having routine blood collections to monitor the status of the transplant and your disease. There are aspects often associated with having blood samples taken that can be viewed as unpleasant. These include may include fainting, pain and/or bruising. Rarely, there may be a small

blood clot or infection at the site of the needle puncture. The blood pressure cuff may also cause discomfort or bruising to the upper arm.

Another risk may be loss of confidentiality. Every effort will be made to keep your study records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your study information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the study director about whether this could apply to you.

C2. ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

This study will not be of direct benefit to you, but we hope the information from this study will help us develop a better treatment for preventing cancer cells from spreading.

D1. ARE THERE ANY COSTS TO BEING IN THE STUDY?

There are no costs to you for any activities in this study.

D2. WILL I BE PAID FOR BEING IN THE STUDY?

You will not be paid for participating in this study.

D3. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE STUDY?

If you have been following directions, the injury is directly related to the research, and not the result of an underlying condition, then MCW will compensate you for the injury.

If you think you have been injured because of this study, let the study doctors know right away by calling 414-805-6800.

D4. WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

- If you have more questions about this study at any time, you can call Dr. Knight at 414-805-6800.
- If you have questions about your rights as a study participant, want to report any problems or complaints, obtain information about the study, or offer input you can call the Medical College of Wisconsin/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this study?

To do this research study, we need your permission to collect and share some of your health information, or you cannot be in the study. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect information needed for the study.

The health information we will collect and use for this study is:

- Hospital/ Medical Records
- Biological Samples

E2. Who will see the health information collected for this study?

The only MCW/Froedtert Hospital employees allowed to handle your health information are those on the study team, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

The study team may share your information with people who don't work at MCW/Froedtert Hospital because they planned, pay for, or work with us on this study. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital. For this study, we plan to share information with those doctors, researchers or government representatives working with us on this study at the institutions or companies listed here:

U.S. Food and Drug Administration, Rockville, MD
Any Independent ethics committee, which approved this study
Any Data Safety Monitoring Board appointed to review this study
Other Regulatory Agencies and/or Their Designated Representatives
Those required by law

We may record your research information, including results of tests, procedures or questionnaires done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

We will not use your health information for a different study without your permission, or the permission of a hospital research review board (IRB). Once all personal identification is removed, the information might be used or released for other purposes without asking you. Results of the study may be presented in public talks or written articles, but no information will be presented that identifies you.

E3. What are the risks of sharing this health information?

One risk of taking part in a research study is that more people will handle your personal health information collected for this study. The study team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. Depending on the kind of information being collected, it might be

used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the study director about whether this could apply to you.

E4. How long will you keep the health information for this study?

If you sign this form, we plan to keep your information without any end-date in case we need to check it again for this study.

E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Jennifer Knight, MD at *Medical College of Wisconsin, 8701 Watertown Plank Road, Milwaukee, WI 53226*. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the study. We may still use the information we have already collected.

CONSENT TO PARTICIPATE IN THE STUDY

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The study's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the study team use and share the health information and other information gathered for this study.
- I voluntarily agree to participate in this research study. I agree to follow the study procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**
Name of Legally Authorized Representative (if applicable) *please print*	**Signature of Legally Authorized Representative**	**Date**
Name of Witness (if applicable**)** *please print* (for short form consent process, or consent of blind or illiterate subject)	**Signature of Witness**	**Date**
*** Name of person discussing/ obtaining consent** *please print*	**Signature of person discussing/obtaining consent**	**Date**