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

Name of Study Subject: _____

USE OF ß-HYDROXY-ß-METHYLBUTYRATE (HMB) TO COUNTERACT LOSS OF MUSCLE MASS AND STRENGTH IN OLDER MEN WITH PROSTATE CANCER STARTED ON ANDROGEN DEPRIVATION THERAPY (ADT)

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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, possible risks and benefits to you, your choices, and other important information. If there is anything that 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 being invited to participate in this research study because you are age 60 or older with prostate cancer and you will be starting on androgen deprivation therapy (ADT). ADT is a standard treatment for prostate cancer.

A total of about 80 people are expected to participate in this study at the Medical College of Wisconsin/Froedtert Hospital.

The Director of the study is Kathryn Bylow, MD in the Department of Hematology and Oncology. A study team works with Dr. Bylow. You can ask who these people are.

Dr. Bylow has received funding for this study through a Froedtert & Medical College of Wisconsin Cancer Center Grant.

A2. DO I HAVE TO BE IN THIS STUDY?

You can decide whether to take part in this 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.

A research study is different from routine medical care in three ways: 1) there are extra risks that we will tell you about in this form; 2) you may have some extra medical tests and visits; 3) the study procedures, tests and visits follow a set plan that must be kept.

A3. WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this study is to evaluate if the nutritional supplement ß-Hydroxy-ß-Methylbutyrate (HMB) plus the amino acids arginine and glutamine (AG) will help decrease the loss of muscle size and strength that occurs with the treatment of prostate cancer. HMB and amino acids work together to increase muscle and strength.

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

Research study groups

You will be randomized into one of the two study groups. One group will receive standard of care androgen deprivation therapy (ADT) with the nutritional supplement HMB + AG amino acids (1 packet contains 1.2 g of the amino acid metabolite HMB, 7 g of the amino acid arginine, and 7 g of the amino acid glutamine) and one group will receive standard of care ADT. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either group. Neither you nor the study doctor can choose what group you will be in.

Summary of Study Procedures:

- HMB+AG: If you are randomized to receive HMB+AG, you will take 1 packet of the nutritional supplement 2 time(s) per day. The nutritional supplement should be mixed with 8-10 fluid ounces of water or other liquid such as fruit juice. You can also mix the nutritional supplement in yogurt or applesauce. It should not be mixed with very hot or very cold liquid. You will be asked to keep a diary to record the date, number of packets taken, and time taken. You will be asked to return the completed diary and empty HMB + AG packets at your 3 month visit.

The following procedures will be done at the start of the study and 3 months after the start of the study:

- Functional assessments: These assessments include hand strength, tests of balance, walking ability and speed and take about 5-10 minutes to complete. These assessments will be done by a member of the research team.

- **Physical Activity Measurement:** You will be asked to wear an activity monitor for 5-7 days. This is a small portable device about the size of a pager that records movements. It is to be worn around the waist. You will also be asked to keep a simple diary of your physical activities. After you have completed the monitoring you can return the instrument to us on your next training day. You will not have to wear the device to sleep, while bathing, or for formal gatherings.

- Dual-emission X-ray absorptiometry (DXA) scan: A DXA scan is a painless test that measures the density of bones. Generally, the denser your bones are the stronger they are, and the less likely they are to break. DXA scans help find out whether you have osteoporosis or are at risk of developing it. They can also be used to detect other bone disorders and conditions, and to monitor the relative amounts of body fat and muscle in your body. Men who are getting treated for prostate cancer are at a risk of loss of bone strength. You will have 2 DXA scans during this study – once at the start of the study and once 3 months after the start of the study. You will be asked to lie down on a scan table and remain motionless. A scanner will pass over you. The procedure will take a total of 10-15 minutes to complete.

B2. HOW LONG WILL I BE IN THE STUDY?

You will be in this research study for about three months.

B3. CAN I STOP BEING IN THE STUDY?

You are free to withdraw from the study at any time. If you leave, your regular medical care will not change. If you are thinking about leaving, please tell the study doctor. You will be asked to return your diary any unused nutritional supplements or empty nutritional supplement containers.

The study doctor may take you out of this study at any time. This would happen if:

- They think it is in your best interest.
- You do not follow the study rules.
- The whole study is stopped.

If this happens, the study doctor will tell you.

B4. ARE THERE ANY SPECIAL INSTRUCTIONS WHILE I AM IN THE STUDY?

If you are randomized to receive HMB+AG, please tell all of your healthcare providers that you are taking this nutritional supplement.

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

There are risks to taking part in any research study. There also may be problems (side effects) we do not know about yet, the HMB+AG or how it combines with other drugs you are taking. If we learn about new important side effects, we will tell you.

We watch everyone in the study for problems (side effects). **You need to tell the study doctor or a member of the study team immediately if you experience any problems, side effects, or changes in your health.**

C2. RISKS OF HMB+AG

HMB+AG may cause problems (side effects). Side effects may be mild or very serious. Some can last a long time or never go away.

Rare side effects (<10%)
Based on prior studies, those patients who receive HMG+AG vs placebo may have a higher incidence of dry scalp and heartburn. No other significant side effects have been reported.

C3. OTHER RISKS OF THIS RESEARCH STUDY

Other procedures that are part of the study also involve some risks:

Functional assessments
Functional assessments have been shown to be very safe in the geriatric patient population. It is possible that you could trip during the balance/walking test and injure yourself, although the risk is very small. A member of the research team will be standing with you at all times for safety.

Imaging
The DXA scan uses low level x-rays for imaging. It is possible that you may experience some anxiety as a result of imaging, although chance of this is minimal. Patients may experience mild discomfort as a result of lying flat for a period of time on hard surface for both DXA scans.

Confidentiality
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.

C5. ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

We don't know if this study will help you. Your condition may get better but it could stay the same or even get worse. We hope the information from this study will help us develop better treatments for prostate cancer.

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

Some of the medical care that you will receive in this study is considered routine care for your condition and would be recommended whether you join the study or not. Costs for routine care such as physical exams and the standard treatment with Androgen Deprivation Therapy will be billed to you or your insurance carrier. Activities / costs that are part of the study will not be billed to you or your insurance company. These are the cost of the HMB+AG and DXA scans. Some insurers will not pay for drugs, tests or hospitalization that are part of research studies, so check with your insurer before you join this study. If you have questions regarding study costs, please contact Dr. Bylow.

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

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

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this study. You are free to say yes or no. If you do not join this study, your doctor can discuss other healthcare choices with you.

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE STUDY?

If we learn any important new information about the supplement HMG+AG that might change your mind about being in the study, we will tell you about it right away. You can then decide if you want to stay in the study.

D5. WHAT HAPPENS IF I AM HARMED BECAUSE I TOOK PART IN THE STUDY?

No funds have been set aside to pay any costs if you become ill or are harmed because of this study. If you think that you have become ill or were harmed because of this study, let the study doctors know right away by calling 414-805-6800. By signing this form, you do not give up your right to seek payment for harm you receive while participating in this study.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

- If you have more questions about this study at any time, you can call Dr. Bylow 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 MCW/Froedtert Hospital Research Subject Advocate at 414-456-8844.

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 use 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 and use information needed for the study.

The health information to be collected and used for this study is:

- ⇨ Hospital/Medical Records
- ⇨ Physician/Clinic Reports
- ⇨ Lab and/or Pathology Reports
- ⇨ Radiological Reports
- ⇨ Biological Samples
- ⇨ Data Previously Collected for Clinical Purposes

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.

We may record your research information, including results of tests and procedures 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 personal 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 doctor 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 an 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 Dr. Bylow at Froedtert & Medical College of Wisconsin, Division of Hematology and Oncology, 9200 W. Wisconsin Avenue, 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.

FOR MORE INFORMATION ABOUT THE STUDY

You can get more information about this study on the Federal government's web site for clinical trials, at http://www.ClinicalTrials.gov (trial number NCT01607879) as required by U.S. Law, or by asking the study team for a printed copy. This website will not include information that can identify you. At most, the website will include a summary of the results. You may search this website at any time.

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**

** A member of the study team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol. In all research study protocols the Principal Investigator is responsible and accountable for the study.*