Research Consent Form for Social and Behavioral Research
Name:DOB:
Dana-Farber/ Harvard Cancer Center
BIDMC/BWH/CH/DFCI/MGH/Partners Network Affiliates OHRS 09.10.08

Protocol Title: Medical Questionnaire and Tissue Banking For Multiple Myeloma, Waldenstrom Macroglobulinemia and Related Disorders

DF/HCC Principal Research Investigator / Institution: Irene M. Ghobrial, MD / DFCI

Consent for Patients with MM, WM, MGUS, sMM, or LPL

A. INTRODUCTION

We are inviting you to take part in a research study because you have Multiple Myeloma (MM), Waldenstrom's Macroglobulinemia (WM), a distinct B-cell lymphoproliferative disorder, IgM monoclonal gammopathy of undetermined significance (MGUS), Smoldering MM, or lymphoplasmacytic lymphoma (LPL). Research is a way of gaining new knowledge. A person who participates in a research study is called a "participant." This research study is evaluating bone marrow, buccal (cheek cell sample) and peripheral blood samples, along with clinical data from patients with MM, WM, or other LPL, in order to better direct our efforts in designing more specific, more effective and less toxic therapies.

It is expected that about 1,000 people will take part in this research study.

An institution that is supporting a research study either by giving money or supplying something that is important for the research is called the "sponsor." The sponsors of this protocol include the International Waldenstrom Macroglobulinemia Foundation and the Ghobrial Lab. They are providing the funding for the research study.

This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of the research study, alternatives to participation, and your rights as a research participant. The decision to participate is yours. If you decide to participate, please sign and date at the end of the form. We will give you a copy so that you can refer to it while you are involved in this research study.

We encourage you to take some time to think this over and to discuss it with other people and your doctor and to ask questions now and at any time in the future.

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B. WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this study is to obtain bone marrow, buccal (cheek cell sample) and peripheral blood samples, along with clinical data from patients with Multiple Myeloma (MM), Waldenstrom's Macroglobulinemia (WM), smoldering MM, and other lymphoplasmacytic lymphomas (LPL) including but not limited to MGUS and IgG or IgA LPL. These samples will become part of a tissue bank and will be used in ongoing studies to find out more about the causes and biology of MM, WM and LPL; to identify what factors result in normal cells becoming cancer; to determine how to improve treatment options; to study how the immune system identifies abnormal cells (tumor cells); and to evaluate the immune function in these diseases. We will also study the tumor cells at the level of your genes to develop new treatment strategies as well as to better understand how biologic differences affect patient outcomes. These studies will help us better direct our efforts in designing more specific, more effective and less toxic therapies.

Because many studies are preliminary and results will not be meaningful or beneficial to your health or disease management, no results of this study will be given to you or included in your medical record.

C. WHAT OTHER OPTIONS ARE THERE?

Taking part in this research study is voluntary. You have the option of not participating in this research study.

D. WHAT IS INVOLVED IN THE RESEARCH STUDY?

If you take part in this study, you will first be asked to complete two medical questionnaires which includes your demographics, diagnosis and treatment history, medical history, lab results, symptoms experienced as well as environmental, dietary and family history data. You may choose to not answer any questions within the survey.

Once the completed medical questionnaires and the two signed consent forms are received at Dana-Farber, you will be sent the instructions for the tissue banking procedure, which involves donating bone marrow, buccal (cheek cell sample) and blood samples. These will be collected only at times when necessary clinical bone marrow samples are obtained and will not require an extra visit to your doctor. Instructions for the collection of bone marrow, buccal

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(cheek cell sample) and blood will be sent, along with the collection kits and shipping instructions.
You are not being asked to undergo a separate procedure for this blood or bone marrow aspirate collection. Additional bone marrow aspirates may cause additional discomfort; however there is no significant extra risk to obtain samples for this study.

We are also requesting permission to collect medical information from your record and link this information to your specimens so that we may better understand your response to treatment. For samples obtained prior to beginning therapy, this information might also allow us to develop new ways of predicting responses to therapy. We are also requesting your permission to store samples of blood and bone marrow samples to establish a tissue bank for future research related to these diseases. Once your samples are received at the Ghobrial lab, they will be de-identified; any of your personal health information identifiers will be removed from your sample(s), it will be assigned a unique number and stored in the tissue bank located within the Ghobrial Lab at DFCI. There will be a database that links your sample number to your name and personal health information, however this database will be password protected. Only Dr Irene Ghobrial and designated study team members will have access to this database. If outside investigators request to use your sample(s), they will only be sent the de-identified sample(s). If the outside investigator asks for clinical data that is associated with your sample(s), this will be provided, however we will not provide any identifying information (name, date of birth, address, etc) with your sample(s).

In the event that you choose to have your sample(s) and personal health information withdrawn from the bank, please send a letter to Dr Irene Ghobrial outlining your request. If this should occur, your sample will be removed from the bank and destroyed. Your personal health information will also be completely removed from the database. If your sample has been released to an outside investigator, we will not be able to retrieve and destroy that sample.

The tumor sample may be obtained at diagnosis, during treatment and/or at the time of relapse. The timing of sample collections will coincide with other bone marrow tests required to assess the response to therapy or any other clinical purpose. Typically, samples may be collected during clinical procedures that occur once or twice a year. The volume of bone marrow at each collection will be approximately 1-2 tablespoons. Buccal samples may be collected once and involve a swabbing back and forth of the inside of the cheek. The volume of

blood collected at each blood draw will be approximately 1-2 tablespoons. Each sample will be assigned a unique identifier, to preserve patient confidentiality.

Occasionally, laboratory research on human blood, tumors or other tissue may result in discoveries that become the basis for new products. There are no plans to reimburse you should there be commercial developments made with, or through the use of your specimens.

E. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

Risks and side effects related to **any blood draw** include the following:

- Temporary soreness and redness of the vein
- Black and blue marks at the blood draw site that may take several days to heal.

Pro-longed blood draws have the additional risks of taking additional time which may increase the level of discomfort.

Risks and side effects related to **any bone marrow aspirate** include the following:

- Pain
- Redness
- Black and blue at the needle insertion site
    - Very rarely, the following may occur
        - Infection
        - Nerve injury
        - Aspiration needle breakage

A pro-longed bone marrow aspirate may increase the level of discomfort because the added pulls take additional time.

Risks and side effects related to **any buccal (cheek cell) samples** include the following:

- Redness at the site the swab rubbed backwards and forwards.

During the research study, you will be provided with any new information that may affect your health or willingness to participate. You may be asked to sign a new consent form that shows that you have been informed of new information relating to this research study.

F. WHAT ARE THE BENEFITS OF THE RESEARCH STUDY?

If you agree to take part in this study, there will be no direct medical benefit to you. We hope the information learned from this study will benefit other patients with your disease in the future.

G. CAN I STOP BEING IN 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. Leaving the research study will not affect your medical care. You can still get your medical care from your hospital or study doctor.

If you choose to not participate, or if you are not eligible to participate, or if you withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

H. WHAT ARE THE COSTS?

Because the samples for this study will be obtained during already scheduled procedures, you will not incur any additional costs as a direct result of your participation in this study or from the testing of specimens. Please ask the investigator and/or your doctor about any concerns or insurance problems. You will not be charged for laboratory studies that are part of this research study, including the costs associated with tissue banking or record collecting. You or your insurance company will, however, be charged for any other portion of your care, including bone marrow procedures and blood draws that are considered standard care.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call your insurance company for information before having any procedures done.

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below.

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http://www.cancer.gov/clinicaltrials/learning/insurance-coverage

I. WHAT HAPPENS IF I AM INJURED OR SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

There are no plans for DF/HCC to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research Investigator's name and phone number are listed in this consent form.

J. WHAT ABOUT CONFIDENTIALITY?

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

Medical information created by this research study may become part of your hospital medical record. Information that does not become part of your medical record will be stored in your study file. It may also become part of a DF/HCC research database. The results of this research study may be published. You will not be identified in publications without your permission.

K. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the research Investigator or study staff as listed below:

Dana-Farber Cancer Institute

- Irene M. Ghobrial, MD: 617 – 632 – 4198; DFCItissuebank@gmail.com

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at DFCI (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

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L. PRIVACY OF PROTECTED HEALTH INFORMATION

Federal law requires Dana Farber/Harvard Cancer Center (DF/HCC) and its affiliated research Investigators, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions ("protected health information"). If you enroll in this research study, your "protected health information" will be used and shared with others as explained below.

1. **What protected health information about me will be used or shared with others during this research?**

   - Existing medical records
   - New health information created from study-related tests, procedures, visits, and/or questionnaires

2. **Why will protected information about me be used or shared with others?**

   The main reasons include the following:
   - To conduct and oversee the research described earlier in this form;
   - To ensure the research meets legal, institutional, and accreditation requirements;
   - To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
   - Other reasons may include for intervention, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care.

3. **Who will use or share protected health information about me?**

   - DF/HCC and its affiliated research Investigators and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

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4. With whom outside of DF/HCC may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor(s) of the study, and its subcontractors
- Other research Investigators and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes.
- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable

Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

5. For how long will protected health information about me be used or shared with others?

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

6. Statement of privacy rights:

- You have the right to withdraw your permission for the research Investigators and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure

quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: Whom do I contact if I have questions about the research study?"

- You have the right to request access to your protected health information that is used or shared during this research and that is related to your intervention or payment for your intervention, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: "Whom do I contact if I have questions about the research study?"

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M. DOCUMENTATION OF CONSENT

My signature below indicates my willingness to participate in this research study and my understanding that I can withdraw at any time.

By signing this consent for, I agree to:

1. Allow researchers at Dana-Farber / Harvard Cancer Center institutions to collect and store information from my chart, including medical records, laboratory tests, and pathology reports.

(Please initial one) _____YES _____NO

2. Provide an extra sample of blood, buccal (cheek cell) sample and bone marrow aspirate when indicated for clinical (non-research) reasons and store this tissue for future study.

(Please initial one) _____YES _____NO

3. Allow researchers at Dana-Farber / Harvard Cancer Center to contact me in the future for an update on my disease and/or to provide additional blood and bone aspirate samples..

(Please initial one) _____YES _____NO

4. Allow researchers at Dana-Farber / Harvard Cancer Center to contact me in the future to discuss potential studies which may be appropriate for me.

(Please initial one) _____YES _____NO

_____	_____
Printed Name of Participant	Date of Birth
_____	_____
Signature of Participant	Date
_____	_____
Signature of Principal Investigator	Date

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To be completed by person obtaining consent:

The consent discussion was initiated on _____ (date).

☐ A copy of this signed consent form will be given to the participant or legally authorized representative, or, where the participant is a minor, the participant's parent or legal guardian.

For Adult Participants

☐ The participant is an adult and provided consent to participate.

☐ Participant (or legally authorized representative) is a non-English speaker and signed the translated Short Form in lieu of English consent document:

As someone who understands both English and the language spoken by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.

Signature of Interpreter/Witness: _____

Printed Name of Interpreter/Witness: _____

Date: _____

☐ Participant is illiterate

The consent form was read to the participant who was given the opportunity to ask questions.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

☐ The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

☐ gave permission for the adult participant to participate

☐ did not give permission for the adult participant to participate

Signature of Individual obtaining consent: _____

Printed name of above: _____

Date:

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