Participant Informed Consent for Clinical Research

Study title for participants: A Study of a Plant-Based Diet in People with Monoclonal Gammopathy of Undetermined Significance (MGUS) or Smoldering Multiple Myeloma (SMM)

Official study title for internet search on http://www.ClinicalTrials.gov: A Pilot Plant-Based Dietary Intervention in Overweight and Obese Patients with Monoclonal Gammopathy of Undetermined Significance (MGUS) and Smoldering Multiple Myeloma (SMM) - The Nutrition Prevention (NUTRIVENTION) Study

Lead Researcher: Urvi Shah, MD (212-639-7016)

Overview and Key Information

Why is this study being done?

We are asking you to take part in a clinical research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this study because you have monoclonal gammopathy of undetermined significance (MGUS) or smoldering multiple myeloma (SMM). People with MGUS have an abnormal protein—known as monoclonal protein or M protein—in their blood. SMM is a pre-cancerous (before cancer) disease that can get worse and become multiple myeloma, a cancer of a white blood cell (called a plasma cell) that grows out of control. In addition to having SMM or MGUS, you are overweight. Because of your disease and your weight, you are at high risk of developing multiple myeloma.

Researchers think that a plant-based diet may prevent multiple myeloma from developing in overweight people with MGUS or SMM. A plant-based diet includes foods that are mainly from plants (for example, fruits, vegetables, nuts, beans, and whole grains). Studies have shown that a plant-based diet can lead to weight loss, improve the balance of hormones (hormonal balance), and reduce inflammation in the body, and researchers think these positive effects could protect against cancer growth.

We are doing this study to find out whether a plant-based diet is practical (feasible) for overweight people with MGUS or SMM, and we will look at whether the diet is effective in preventing multiple myeloma in participants.

Taking part in this study is your choice.

You can choose to take part or not to take part in this study, and you can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document presents important information to help you make your choice. Please take time to read it carefully. Talk with your doctor, family, or friends about the risks and benefits of taking part in this study. It's important that you have as much information as you need, and that all your questions are answered.

What is the usual approach to my MGUS or SMM?

People with MGUS or SMM do not usually receive treatment. Because people with MGUS or SMM have a higher risk of developing multiple myeloma, they are watched very closely by their doctors for signs of multiple myeloma.

What are my other choices if I decide not to take part in this study?

- You may choose to have the usual approach described above
- You may choose to take part in a different research study, if one is available

What will happen if I decide to take part in this study?

If you decide to take part in this study, a company called Plantable will ship premade frozen plant-based meals to your home each week for a total of 12 weeks. You will get 6 dinners and 6 lunches of plant-based meals each week. You will receive a food log (diary) with your meal shipment and a food diary from the study team. You will record the food you have been eating during the week. You will receive dietary education and counseling from a research dietitian every 2 weeks for the 12 weeks that you are receiving the premade plant-based meals. These meetings will be over the phone (or by video conferencing) and at visits to the clinic, if these visits are possible. Your dietitian will discuss your food diaries with you, and you will complete questionnaires about your diet and health.

At the end of the first 12 weeks, your research dietitian will meet with you in the clinic or over the phone (or by video conferencing) and encourage you to continue with a plant-based diet for the next 12 weeks. The research dietitian will also check in with you on Week 18 (over the phone) and Week 24 (either at the clinic or over the phone).

You will return to the clinic for an End-of-Study visit at Week 52 (about 1 year after you started this study).

When you come to the clinic during this study, you will have various tests and procedures, including blood and bone marrow collection for research purposes. Throughout the study, you will collect your stool at home so we can test it for research purposes. You will find more detailed information about tests and procedures in the section *What extra tests and procedures will I have if I take part in this study?*

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important to think carefully about these as you make your decision.

Risks

We want to make sure that you know about a few key risks right now. We will also give you more information in the *What risks can I expect from taking part in this study?* section of this consent form.

There is also a risk that you could have side effects from the plant-based meals. These side effects are rare, but possible.

Some of the possible side effects of a plant-based diet that the study doctors know about are:

- Nausea
- Vomiting
- Loose stool or diarrhea
- Pain or discomfort in the upper stomach area (dyspepsia)

- Feeling heavy in the stomach because of gas or fluid (bloating)

There may be some risks that the study doctors do not yet know about.

Benefits

Research studies have shown that a plant-based diet can lead to weight loss, improve hormonal balance, and reduce inflammation in the body**.** However, no study has tested a plant-based diet in people with MGUS or SMM. The plant-based diet may help you lose weight and protect you against cancer growth. The diet may have other positive effects, such as reducing your risk of heart problems. However, your condition may get worse during this study. What we learn from this study may help other people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop participating in the study at any time.

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

If you decide to stop, let the study doctor know as soon as possible. It's important that you stop safely.

If you stop, you can decide whether to let the study doctor or a member of the study team continue to contact you to ask questions about your health. We will not be able to withdraw information about you that has been used or shared with others before you informed us of your decision to stop.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes, and the study is no longer in your best interest
- New information becomes available, and the study is no longer in your best interest
- You do not follow the study rules
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), US Food and Drug Administration (FDA), or the study sponsor, Memorial Sloan Kettering Cancer Center (MSK). The study sponsor is the organization that oversees the study.

It is important that you understand the information in this informed consent document before you make a decision about participating in this clinical trial. Please read, or have someone read to you, the rest of this document. If there is anything that you don't understand, ask the study doctor or nurse for more information.

What is the purpose of this study?

This study will test whether a plant-based diet is practical (feasible) for overweight people with monoclonal gammopathy of undetermined significance (MGUS) or smoldering multiple myeloma (SMM). We will decide how practical the diet is by looking at how much weight participants lose and how well they are able to stick to the diet. We will also determine whether the diet is effective in preventing

multiple myeloma in participants. In addition, we will look at how safe the plant-based diet is for participants, and see if the diet affects participants' quality of life.

Researchers have found that people with MGUS or SMM who are overweight and on diets that are high in sugar and low in plant-based foods have a greater risk of developing multiple myeloma. Research studies have shown that a plant-based diet can lead to weight loss, improve hormonal balance, and reduce inflammation in the body. However, no study has tested a plant-based diet in people with MGUS or SMM. This study will provide useful information about whether a plant-based diet may protect people with MGUS or SMM against cancer growth.

The premade frozen plant-based meals used in this study will have a low glycemic index (they won't cause your blood sugar to spike) and contain vegetables, whole grains, and plant-based fats that have undergone minimal (little) processing. The meals will be provided by Plantable, a company that is based in Brooklyn, NY.

About 20 people will take part in this study at Memorial Sloan Kettering Cancer Center (MSK).

What are the study groups?

All study participants will have MGUS or SMM. All participants will follow a 24-week plant-based diet and have 11 study visits in the clinic or over the phone for up to 1 year.

What extra tests and procedures will I have if I take part in this study?

Before you begin the main part of the study:

The study doctor will review your medical records and the results of your exams, tests, and procedures to see if it is safe for you to take part in the study. This first part of the study is called screening. Most of the screening exams, tests, and procedures are part of the usual care that you would have if you were not in a study.

During the screening visit, you will have your first consultation visit with your research dietitian. The dietitian will provide you with dietary education and counseling.

The tests and procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- Urine or blood pregnancy test, if you are a woman who is able to have children
- Bone marrow biopsy and/or aspiration. These procedures may need to be repeated for research purposes. Bone marrow biopsy involves collecting spongy tissue inside the bone. Bone marrow aspiration involves taking a sample of the liquid part of the soft tissue inside the bone.
- You will receive stool collection kit with instructions you can use at home. Throughout the study, you will collect your stool at home and bring it to the clinic. We will use your samples to research different kinds of bacteria that are present in your stool.
- Study questionnaires to be completed on paper, including:
  - Block questionnaire, which asks about your diet and physical activity. It will take about 15 minutes to complete this questionnaire.
  - QLQ-C30 questionnaire, which asks about your general health and how you are feeling. It will take about 10 minutes to complete this questionnaire.

- Collection of blood (about 3 tablespoons) for biomarker research testing. A biomarker is a biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition.

During the study:

Plantable will ship premade frozen plant-based meals to your home each week for a total of 12 weeks. You will get 6 dinners and 6 lunches of plant-based meals each week. You will receive instructions on how to store and reheat your food with your shipments. We will ask you to prepare your own plant-based breakfasts every day, and you will need to prepare all your plant-based meals during 1 day a week. You will receive educational content and recipes by email in the first month of the study to help you prepare plant-based meals. If feasible, you will also have access to Plantable phone application, which includes recipes, meal planning, and self-tracking tools. A Plantable coach who can guide you with your meals will be available to you by phone (or texting) every day from 7:00 AM to 11:00 PM for 24 weeks.

You will receive a food log (diary) with your meal shipment and a food diary from the study team. We will ask you to record the meals you have been eating into your food diaries. You will receive dietary education and counseling from a research dietitian every 2 weeks for the 12 weeks that you are receiving the premade plant-based meals. These meetings will be over the phone (or by video conferencing) and at visits to the clinic, if these visits are possible. During the meetings, your research dietitian will discuss your food diaries with you, answer your questions, and provide help with your diet.

At the end of the first 12 weeks, your research dietitian will meet with you in the clinic or over the phone (or by video conferencing) and encourage you to continue with a plant-based diet for the next 12 weeks. The research dietitian will also check in with you on Week 18 (over the phone) and Week 24 (either at the clinic or over the phone). You will not receive premade meals during the second 12 weeks of the study period, but you will continue to have access to a Plantable coach, and phone application if you require it. You will fill out a food diary before Weeks 18 and 24.

While you are on the plant-based diet we will ask you to take vitamin B12 supplement, and we may ask you to take vitamin D supplement if needed. The study doctor will let you know when and which vitamins you will take.

<u>Exams, Tests, and/or Procedures</u>

You will have exams, tests and procedures during the main study. The procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- Research dietitian visits. Please bring your food diaries to these visits.
  - In clinic or over the phone (or by video conferencing): Day 1 and Weeks 4, 8, 12, and 24
  - Over the phone: Weeks 2, 6, 10, and 18
- Collection of stool. You will bring your stool to the clinic on Weeks 4, 12, 24, and the End-of-Study visit, which is described below.
- Bone marrow biopsy and/or aspiration if the study doctor thinks these procedures are necessary. These procedures can take place at the End-of-Study visit, which is described below.
- Study questionnaires on Weeks 4, 12, and 24

- Collection of blood (3-4 tablespoons each time) for biomarker research testing on Weeks 4, 8, 12, and 24

End-of-Study visit:

You will have an End-of-Study visit 1 year after the start of the study. The procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- Study questionnaires
- Collection of blood (3-4 tablespoons) for biomarker research testing

After completing the visit at Year 1, your participation in the study will end.

If you develop multiple myeloma at any time during the study, you will stop the rest of the study activities and have an early End-of-Study visit. The procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- Research dietitian visit
- You will bring your stool to the End-of-Study visit
- Bone marrow biopsy and/or aspiration
- Study questionnaires
- Collection of blood (3-4 tablespoons) for biomarker research testing

A Study Calendar that shows how often you will have these exams, tests, and procedures is provided at the end of this consent form. The calendar also includes exams, tests, and procedures that are part of your usual care.

Will I receive the results of my research tests?

You will not receive the results of any tests done for research purposes during this study.

What risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work, school, or at home, and you may spend more time than usual in the hospital or doctor's office
- You may be asked sensitive or private questions that you do not usually discuss
- People who should not see your personal or health information will get access to it and share it

The study doctor will be testing your blood throughout the study, and he or she will let you know if changes occur that may affect your health. For example, the study doctor will let you know about improvement in blood sugars if you have diabetes/prediabetes. This improvement may require adjustment of your diabetes medications. The study doctor will also let you know about improvement in cholesterol and lipids.

There is also a risk that you could have side effects from the study approach.

Important information about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, and some may last a long time.

Important information about how you and the study doctor can make side effects less of a problem for you:

- If you notice or feel anything different, tell the study doctor. He or she can check to see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust your diet to try to reduce your side effects.

The section below includes the possible side effects that researchers know about. There may be other side effects that the doctors do not yet know about. If important new side effects are found during this study, the study doctor will discuss them with you.

Possible side effects of plant-based diet:

These side effects are possible but rare:

- Nausea
- Vomiting
- Loose stool or diarrhea
- Pain or discomfort in the upper stomach area (dyspepsia)
- Feeling heavy in the stomach due to gas or fluid (bloating)

Possible risks and discomfort associated with bone marrow aspiration/biopsy procedures: This procedure may cause pain or bruising where the needle enters the skin (above the hip bone) or when the needle is removed. You may also experience bleeding, swelling, dizziness, and infection. You will be given a medication for pain relief, as needed.

Possible risks of completing questionnaires/surveys: You may feel uncomfortable, stressed, or upset while you are filling out the questionnaire/survey. Tell the study doctor or a member of the study team if you skipped or chose not to answer any of the questions, or if you decide that you do not want to complete the questionnaire/survey.

Let the study doctor know about any questions you may have about possible side effects. You can ask the study doctor questions about side effects at any time.

What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Keep your study appointments
- Tell the study doctor about:
    - All medications and any supplements you are taking
    - Any side effects from these medications or supplements
    - Any doctor visits or hospital stays outside of this study
    - Whether you have been or are currently in another research study
- Let the study doctor know if you skipped or chose not to answer any of the questions in the questionnaire/survey.
- Avoid food products or supplements that are not plant-based.

Is there a conflict of interest for this study?

This study is sponsored by Memorial Sloan Kettering Cancer Center (MSK). There are no known investigator and/or institutional conflicts of interest for this study.

What are the costs of taking part in this study?

You will not have to pay for the premade frozen plant-based meals or for tests and procedures done only for research purposes, as described above in *What extra tests and procedures will I have if I take part in this study?* These tests and procedures include:

- Research dietitian visits
- Urine or blood pregnancy test
- Bone marrow biopsy and/or aspiration (if repeated for research purposes)
- Collection and testing of stool
- Study questionnaires
- Collection and testing of blood for research purposes

It is possible that the premade frozen plant-based meals may not continue to be supplied while you are in the study. This possibility is unlikely, but if it occurs, your study doctor will talk with you about your options.

You and/or your health plan/insurance company will have to pay for all the other costs of treating your MGUS or SMM while you are in this study. These charges include the costs of insurance co-pays and deductibles, as well as tests, procedures, or drugs that you get during the study to monitor your safety, and to prevent or manage any side effects.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this clinical trial. Also find out if you need approval from your health plan before you can take part in this study.

The study doctor or nurse can help you find the right person to talk to if you are not sure which costs will be billed to you or your insurance provider.

Will I receive payment for taking part in this study?

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

Your biospecimens (blood, bone marrow, stool) may be used in the development of new tests, drugs, or other products for sale. If they are, you will not receive any payment from the sale of these products.

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

You will get medical treatment if you are injured as a result of taking part in this study.

If you think that you have been injured as a result of taking part in this research study, tell the study doctor or the person in charge of the study as soon as possible. The name and telephone number of the person in charge of this research are listed on the first page of this consent form.

We will offer you treatment for research injuries that happen as a result of your taking part in this study. You and/or your health plan will be charged for this treatment. Medical services will be offered at the usual charge. You will be responsible for any costs not covered by your health plan/insurance company.

If you think that your injury was a result of medical error, you keep all your legal rights to receive payment for treating the injury, even though you are in a study.

Who will see my medical information?

Your privacy is very important to us, and the researchers will make every effort to protect it. Trained staff at Memorial Hospital may review your records, if necessary.

Access to your protected health information will be limited to those listed in the Research Authorization form, which is a part of the informed consent process.

Your information may be given out, if required by law. For example, some states require doctors to make a report to the state health board if they find that a participant in a research study has a contagious disease like tuberculosis. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

In the future, your information (data) and biospecimens may be de-identified, which means that your data and/or biospecimens will be assigned a unique code, and the list that links the code to your name will be stored separately from your biospecimens and data. Your de-identified information and biospecimens may be used for research that has not been described in this consent form, and they may be shared with another investigator for future research. You will not be asked if you agree to take part in future research studies.

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. It is possible that your de-identified information from this study will be shared with other researchers outside of MSK, and may be stored in public databases related to research. All requests for data sharing will be reviewed by the study sponsor, and if individual results are included in the data, they will not contain any identifiable information about you, such as your name, address, telephone number, or Social Security number. Your privacy is very important to us and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your information to identify you.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about research studies, or for general information about cancer. You may also call the NCI Cancer Information Service to get the same information at 1-800-4-CANCER (1-800-422-6237).

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.

You can talk to the study doctor about any questions or concerns that you may have about this study, or to report side effects or injuries. You may also contact the lead researcher listed on the first page of this consent.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.


1884

Research Authorization for the Use and Disclosure of Protected Health Information (PHI)

A Study of a Plant-Based Diet in People with Monoclonal Gammopathy of Undetermined Significance (MGUS) or Smoldering Multiple Myeloma (SMM)

Federal law requires Memorial Sloan Kettering Cancer Center (MSK) to protect the privacy of information that identifies you and relates to your past, present, and future medical conditions (protected health information; PHI). We are committed to protecting the privacy of your information.

If you enroll in this research study, your protected health information will be used and shared with others, as explained below. MSK must obtain your permission before using or sharing your protected health information for research purposes. This form helps to make sure that you are informed of the ways in which your information will be used or shared in the future.

Carefully read the information below before you sign this form. By signing this form, you agree to the use and disclosure of your information for this research study.

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

- Your medical records
- Your research records, including new health information created from study-related tests, procedures, visits, and/or questionnaires
- Any health information or clinical data associated with your biospecimens, if the information or data could be reasonably used to identify you. This information or data will be shared only if you have agreed to it by signing this informed consent document.
- HIV-related information, including any information indicating that you have had an HIV-related test; or that you have HIV infection, HIV-related illness, or AIDS; or any information that could indicate that you may have been exposed to HIV. (New York State requires us to obtain your consent to use or share this information.)

2. Who will use or share my protected health information?

MSK will use and share your protected health information. People and offices that deal with research oversight, quality assurance, and/or billing will be able to use and share your protected health information, including:

- The study's Principal Investigator and Co-Principal Investigator: Urvi Shah, MBBS and Alexander Lesokhin, MD
- Your research team at MSK, including the participating investigators, research staff, research nurses, fellows/residents, and clerical support staff
- Any healthcare personnel who provide services to you in connection with this study
- Members and staff of MSK's Institutional Review Board (IRB) and Privacy Board (PB)
- Staff of MSK's Clinical Research Administration, which oversees clinical studies, and Clinical Research Information Technology Group, which manages research databases
- Members of MSK's Data Safety Monitoring Board/Committee and the Quality Assurance Committee

3. With whom outside of MSK may my protected health information be shared?

Although all reasonable efforts will be made to maintain the confidentiality of your protected health information, it may be shared with and used by the following:

- MSK's research collaborators, business partners, subcontractors and agent(s), in the United States or in other countries, working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study intervention.
- Other research doctors and medical centers participating in this research.
- Federal and state agencies, and other domestic or foreign government bodies, if required by law and/or necessary for oversight purposes, including:
    - Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (HHS)
    - US Food and Drug Administration (FDA) and other regulatory agencies responsible for oversight of research
    - National Cancer Institute (NCI)/National Institutes of Health (NIH)
- Other qualified researchers, approved by MSK, who may receive individual research results that do not identify you.

Some of the organizations that may receive your protected health information may not have to satisfy the privacy rules and requirements; they may share your information with others without your permission.

4. Why will my protected health information be used by or shared by MSK or others?

The main reasons for the use or sharing of your information include the following:

- To conduct the study, to monitor your health status, to measure the effects of the drug(s)/device(s)/procedure(s) being studied, and to determine the research results
- To ensure that the research meets legal and institutional requirements
- To develop new tests, procedures, and commercial products
- To enhance research databases, so that scientists can design better research studies to develop new therapies for patients and to gain a better understanding of disease
- To assist with MSK medical treatment, billing, or healthcare operations. For example, medical information produced by this research study will become part of your hospital medical record.

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

There is no set date at which your protected health information that is being used or shared for this research study will be destroyed or no longer used. The information used and created during the study may be analyzed for many years, and it is not possible to know when this analysis will be completed.

6. Statement of privacy rights:

- It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in this research study. However, if you do not sign, it will not affect your ongoing medical treatment or healthcare coverage.

- You have the right to withdraw your permission for MSK to use or share your protected health information. Please note that we will not be able to withdraw all the information about you that already has been used or shared with others to carry out research-related activities such as oversight, or information that is needed to ensure the quality of the study. To withdraw your permission, write to the study doctor listed on the first page of this consent form at: Memorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY 10065. If you withdraw permission for us to use or share your protected health information, you will not be able to continue to participate in this research study.

- You have the right to request access to your protected health information that is being used or shared during this research and that is related to the research or to payment for the research. However, you may access this information only after the study is completed. You may have access to the parts of your medical record that are unrelated to this study at any time. To request this information, please contact the study doctor whose name and telephone number are listed on the first page of this consent form. You may also ask the study doctor to correct any study-related information about you that is wrong.

Notice concerning HIV-related information

Individuals/organizations are prohibited from sharing any HIV-related information about you without your approval, unless they are permitted to do so under federal or state law. You have a right to request the list of people who may receive or use your HIV-related information without your authorization.

If you experience discrimination because of the release or disclosure of your HIV-related information, you may contact the New York State Division of Human Rights at 888-392-3644 or the New York City Commission on Human Rights at 212-306-7500. These agencies are responsible for protecting your rights

Participant Informed Consent/Research Authorization for Clinical Research

Statement of professional obtaining consent

I have fully explained this clinical research study to the participant. In my judgment, and in that of the participant, sufficient information, including risks and benefits, was provided for the participant to make an informed decision. The consent discussion will be documented in the participant's EMR.

Consenting professional must personally sign and date		
Consenting professional's signature		**Date:**
Consenting professional's name (Print)		

Participant's statement

I have read this form that describes the clinical research study. I have also talked it over to my satisfaction with the consenting professional. By signing below, I agree to the following: (1) to voluntarily participate in this clinical research study; (2) to authorize the use and disclosure of my protected health information (data about myself); and (3) to state that I have received a signed and dated copy of this consent form.

Participant must personally sign and date		
Participant signature		**Date:**
Participant name (Print)		

Witness signature (if required)

- ❑ Witness for non-English speaking participant: I declare that I am fluent in both English and in the participant's language, and I confirm that the consent discussion was appropriately interpreted for the participant.
- ❑ Other: I confirm that the consent discussion occurred, and that the participant agreed to participate in this study by signing this form, making his/her mark, or verbally agreeing.

Name of witness: _____

Signature of witness: _____ **Date:** _____

(The name of the witness must be documented in the EMR.)

Interpreter (if required)

Name of interpreter (if present): _____

ID number (if phone interpreter): _____

(The interpreter's name or ID number must be documented in the EMR.)

The participant must be provided with a **signed copy** of this form.

Memorial Sloan Kettering Cancer Center
IRB Number: 21-135 A(3)
Approval date: 11-Apr-2022

Study Calendar:

This calendar shows the exams, tests, and procedures that will be done as part of this research study, as well as the tests and procedures that are part of your usual care.

	Before main study	During main study						End-of-Study visit	
Exam/test/ procedure	Screening	Day 1	Day 8	Week 4	Week 8	Week 12	Week 24	Year 1	Last visit if you develop multiple myeloma
Physical exam	X	X		X	X	X	X	X	X
Routine blood collection	X		X	X	X	X	X	X	X
Pregnancy test (if applicable)	X								
Research blood collection	X			X	X	X	X	X	X
Routine urine tests	X	If your disease gets better, additional urine tests may be done if the study doctor thinks these are needed							
Imaging	X							X	X
Bone marrow biopsy/ aspiration	X							X	X
Stool collection	X			X		X	X	X	X
Research dietitian	X	X		Weeks 2 and 4	Weeks 6 and 8	Weeks 10 and 12	Weeks 18 and 24		X
Questionnaires	X			X		X	X	X	X
Electrocardiogram	X								