

**Efficacy of Curcumin and Piperine in Patients on Active Surveillance for either Monoclonal Gammopathy of Unknown Significance (MGUS), low-risk Smoldering Multiple Myeloma (SMM) or Early Stage Prostate Cancer: A Pilot Study**

**Informed Consent Form**

**P RINCIPAL INVESTIGATORS**

**Brea Lipe, MD**

**Investigational Product: Curcumin C3 Complex**

**IND Number: 1 59223**

**NCT04731844**

**Version 14.0: 02 Nov 2023**



## CONSENT FORM

**TITLE: Efficacy of Curcumin and Piperine in Patients on Active Surveillance for either Monoclonal Gammopathy of Unknown Significance (MGUS), low-risk Smoldering Multiple Myeloma (SMM) or Early Stage Prostate Cancer: A Pilot Study**

**INVESTIGATOR:** Brea Lipe, MD  
601 Elmwood Avenue, Box 704  
Rochester, New York 14642

**STUDY-RELATED  
PHONE NUMBER(S):** 585-275-5863 (24 hours)

**This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully and ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.**

### **Key Information**

- Being in this research study is voluntary – it is your choice.
- You are being asked to take part in this study because you have either early stage prostate cancer, monoclonal gammopathy, or smoldering myeloma for which the current recommendation is careful observation not requiring more intensive treatment.
- The purpose of this study is to determine if the supplement of curcumin plus piperine can prevent or delay your disease from progressing to the point where it requires additional treatment.
- Your participation in this study will last for about 12 months.
- You will be instructed to take two tablets of the study drug twice a day (once in the morning and once in the evening for 12 months). You will be asked to bring the study drug with you to each of your study visits. You will also give a blood and urine sample every three months during this time period.
- There are risks from participating and the study team will monitor you carefully for any side effects of the study drug. See the “Risks of Participation” section in this

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consent form for more information. You should discuss these risks in detail with the study team.

- You might not benefit from being in this research study. The potential benefit to you might be that it will delay or prevent your disease from progressing to the point of requiring more intensive treatment.
- If you do not want to take part in this study you will continue with careful monitoring of your disease or pursue other alternatives after discussion with your treating physician.

### **Purpose of Study**

The purpose of this study is to determine whether the supplement of curcumin plus piperine can prevent or delay the progression of prostate cancer, monoclonal gammopathy of unknown significant (MGUS), or low-risk smoldering myeloma into a more aggressive cancer which requires treatment. Curcumin has anti-inflammatory properties and may prevent cancer and slow the spread of cancer. Piperine is used with curcumin to aid in the absorption by the body of the curcumin. We will also be evaluating a marker in your blood called MIC-1 to determine whether it could be a useful predictor of whether your disease is improving or progressing. In addition, we will be collecting and storing blood and urine samples and would like to keep any leftover samples for future testing.

If you decide to take part in this study, you will be asked to:

- Take two tablets of the study drug twice a day (once in the morning and once in the evening) for 12 months. The study drug should be taken on an empty stomach either one hour prior or two hours after food. You will be asked to bring the study drug with you to each of your study visits. Because of a potential risk of an interaction effecting curcumin levels in your blood, you should avoid eating grapefruit or products containing grapefruit extract.
- Study visits will occur every three months at the Wilmot Cancer Center.
- You will also give 15 mL (one tablespoon) of blood collected by a standard blood draw and a 15 ml (one tablespoon) urine sample every three months during each of your study visits. We would like to keep any leftover samples for storage and future research use. You will be asked to decide to allow this at the end of the consent.

You will continue to be monitored with x-rays and laboratory, such as PSA or serum protein levels, as would be the normal standard of care for your disease.

Information about your study participation and study results may be included in your electronic health record. If you have concerns about this or to obtain more detail, you should discuss this with the study team.

### **Number of Subjects**

Approximately 40 subjects will take part in this study. We will recruit 20 patients with early stage prostate cancer and 20 patients with either monoclonal gammopathy of unknown significance or low-risk Smoldering Multiple Myeloma (SMM).

### **Risks of Participation**

Curcumin with piperine is an over-the-counter supplement with minimal side effects reported at the doses used for this study.

The most common side effects are

- Constipation,
- Indigestion (Dyspepsia),
- Diarrhea,
- Abdominal Gas,
- Heartburn,
- Nausea,
- Vomiting,
- Yellow Colored Stools
- Stomach Ache.
- Mild rash or itching.
- Easy bruising or bleeding.

There are no known serious risks to participation but unknown or unexpected risks can occur with any treatment.

### **Reproductive Risks**

Although there have not been reported toxicities, the safety of the combination of curcumin and piperine in pregnancy is not fully known. You should not get pregnant, breastfeed, or father a baby while in this study. Contraception should be used and any pregnancy should immediately be reported to study investigators. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study. If you are able to have children, you must use effective contraception during treatment on this study to prevent pregnancy or fathering a child. Your study doctor will discuss with you what types of birth control or pregnancy prevention to use while on this study and for how long you will need to use them, to prevent pregnancy.

During the study, if you are having problems with the study drug or are experiencing side effects, you should tell us so that we can determine if it is necessary for you to stop taking the study drug. If you experience significant side effects, please contact us immediately.

You will have a small blood draw at each study visit. Blood draws may cause pain, redness, bruising or infection at the site of the needle stick. Rarely some people faint. The study team member may apply numbing cream to the area so that the needle stick won't hurt as much.

The study team may be notified if you receive other health care services at URM or its Affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of testing conducted for this study:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URM primary care, specialist physician offices) who have a reason to access your electronic health record.
- Health care providers who are involved in your care at a facility that is not part of the University of Rochester Medical Center and its Affiliates and who have reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

### **Benefits of Participation**

You might not benefit from being in this research study. The potential benefit to you from being in this study might be that the study drug is successful in delaying or preventing the progression of your disease.

### **Compensation for Injury**

If you are directly injured by the drug being studied, or by medical procedures needed because of this study, and you receive medical care for the injury, you may need to pay for that care. You will be reimbursed for reasonable and necessary medical costs for such care, but you might not be reimbursed for care covered and paid for by a third party like your health insurance provider, or costs such as required co-payments or deductibles related to that coverage. No other funds have been set aside to pay for such things as lost wages or expenses due to a current underlying illness or condition.

If your research injury is paid for by the University, we will collect your name, date of birth, gender, and Medicare Health Insurance Claim Number or Social Security Number to determine your Medicare status. This information will be used only in accordance with

the law. If you are a Medicare beneficiary, information about the study you are in, and any payments made related to your injury, will be reported to the Centers for Medicare & Medicaid Services (CMS), in accordance with CMS requirements. This information will not be used for any other purpose.

### **Costs**

All study medication and study-related tests will be provided at no cost to you.

However, while study drug is provided free of charge, you and/or your insurance company will be charged for the usual costs associated with preparing and administering drug treatment(s).

You or your insurance company will be billed for any standard medical care given during this research study. You will be responsible for any co-pays, insurance deductibles and/or co-insurance required by your health insurance carrier for your standard medical care. This standard medical care includes any care that you would receive for the treatment of your type of cancer whether you were participating in a study or not, such as:

- Routine clinic visits with your doctor or nurse practitioner
- Tests (Including but not limited to routine items such as: laboratory blood tests, CT, MRI, echocardiograms and bone scans)
- Procedures (Including but not limited to routine items such as biopsies)
- Medications: other standard medications to treat your cancer. This can include other chemotherapies or non-chemotherapy medications used to treat your cancer, and/or medications to treat or prevent side-effects.

You may want to talk with your insurance company about its payment policy for standard medical care given during a research study prior to enrolling on a research study. Depending on how your insurance company processes payments for standard medical care given during a research study, you might have unexpected expenses from being in this study. If your insurance company does not pay for your standard medical care, you will be billed for those charges.

Ask your study doctor to discuss the specific costs that will or will not be covered by the sponsor. This discussion should include who will pay the costs of treating possible side effects.

You will not be charged for MIC-1 biomarker testing, that will be covered by the study.

The study medication will be provided free as part of the study for a duration of one year.

### **Payments**

You will not be paid for participating in this study.

### **Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes**

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will make sure only approved research staff members have access to study information collected. Your name is not linked to the data we collect and we will keep all collected study information in a secure database. Results of the research may be presented in publications or at meetings, but your name will not be used. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

#### *What information may be used and given to others?*

The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Past and present medical records related to the study, including records of external providers that are available via your electronic health record at URMC & Affiliates
- Results of medical tests

#### *Who may use and give out information about you?*

- The study doctor and the study staff
- URMC and Affiliates

#### *Your information may be given to:*

- The Department of Health and Human Services
- The University of Rochester
- The U.S. Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private.

*Why will this information be used and/or given to others?*

- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

*What if I decide not to give permission to use and give out my health information?*

Then you will not be able to be in this research study.

*May I review or copy my information?*

Yes, but only after the research is over.

*How long will this permission be valid?*

This permission will last indefinitely.

*May I cancel my permission to use and disclose information?*

Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

*May I withdraw from the study?*

Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

*Is my health information protected after it has been given to others?*

No. There is a risk that your information will be given to others without your permission.

### **Future Use of Information/Samples**

Your leftover blood and urine might be shared or used for future research studies without additional informed consent. All identifiers will be removed before your blood and urine samples are used or shared. You will be given the option at the end of this consent form to decide if you would like your samples to be stored and used for future research. These optional samples will be stored indefinitely or until they are used up.

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**Circumstances for Dismissal**

You may be withdrawn from the study if your disease becomes worse or if your doctor feels that staying in the study is harmful to your health.

**New Study Information**

If we discover any new information that might make you change your mind about continuing in the study, we will let you know.

**Return of Research Results**

In general, we will not give you any individual results from your participation in the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence. Once the study is completed, we will send you a summary of the results and what they mean. You will not receive your individual results.

**Contact Persons**

For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact: Brea Lipe, MD at 585-275-5863.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

**Voluntary Participation**

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

**Use of E-mail for Communication in Research** When using e-mail to communicate with you in this study, the researcher cannot guarantee, but will use reasonable means to maintain security and confidentiality of e-mail information sent and received. You and the researcher should understand the following conditions, instructions and risks of e-mail use:

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*Conditions for e-mail use:*

- a) E-mail is not appropriate for urgent or emergency situations. The researcher cannot guarantee that any particular e-mail will be read and responded to.
- b) E-mail must be concise. You should schedule an appointment if the issue is too complex or sensitive to discuss via e-mail.
- c) E-mail communications between you and the researcher will be filed in your research record.
- d) Your messages may also be delegated to any member of the study team for response.
- e) The researcher will not forward subject-identifiable e-mails outside of URM and Affiliates without your prior written consent, except as authorized or required by law.
- f) You should not use e-mail for communication regarding sensitive medical information.
- g) It is your responsibility to follow up and/or schedule an appointment if warranted.

*Instructions for e-mail use:*

- a) Avoid use of your employer's computer.
- b) Put your name in the body of the e-mail.
- c) Put the topic (e.g., study question) in the subject line.
- d) Inform the researcher of changes in your e-mail address.
- e) Take precautions to preserve the confidentiality of e-mail.
- f) Contact the researcher's office via conventional communication methods (phone, fax, etc.) if you do not receive a reply within a reasonable period of time.

*Risks of e-mail use:*

Sending your information by e-mail has a number of risks that you should consider. These include, but are not limited to, the following:

- a) E-mail can be circulated, forwarded, stored electronically and on paper, and broadcast to unintended recipients.
- b) E-mail senders can easily misaddress an e-mail.
- c) Backup copies of e-mail may exist even after the sender or the recipient has deleted his or her copy.
- d) Employers and on-line services have a right to inspect e-mail transmitted through their systems.
- e) E-mail can be intercepted, altered, forwarded, or used without authorization or detection.
- f) E-mail can be used to introduce viruses into computer systems.

**CONSENT TO FUTURE USE OF INFORMATION / SAMPLES**

May we share your blood and urine samples, health information and genomic information with other researchers to study your disease?

Yes                      No

May we share your blood and urine samples, health information and genomic information with other researchers for future research projects related to other topics?

Yes                      No

## **SIGNATURES/DATES**

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

## **Subject Consent**

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

\_\_\_\_\_  
Subject Name (Printed by Subject)

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

## **Person Obtaining Consent**

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

\_\_\_\_\_  
Name and Title (Print)

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

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**This is a representation of an electronic record that was signed electronically.**

**This page is the manifestation of the electronic signature(s).**

## Document History

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17 Sep 2024	13:39 EDT	Sargent, Susan	Viewed the Document
17 Sep 2024	13:35 EDT	Ali, Amar	Viewed the Document
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17 Sep 2024	13:35 EDT	Ali, Amar	Viewed the Document
17 Sep 2024	13:35 EDT	Ali, Amar	Viewed the Document
17 Sep 2024	13:35 EDT	Ali, Amar	Viewed the Document
17 Sep 2024	13:34 EDT	Ali, Amar	Viewed the Document
17 Sep 2024	13:34 EDT	Ali, Amar	Viewed the Document
17 Sep 2024	13:15 EDT	Fung, Chunkit	Viewed the Document
17 Sep 2024	13:15 EDT	Fung, Chunkit	Viewed the Document
17 Sep 2024	13:15 EDT	Fung, Chunkit	Viewed the Document
17 Sep 2024	13:15 EDT	Fung, Chunkit	Viewed the Document
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17 Sep 2024	13:14 EDT	Fung, Chunkit	Viewed the Document
17 Sep 2024	13:14 EDT	Fung, Chunkit	Viewed the Document
17 Sep 2024	12:59 EDT	Rashid, Hani	Viewed the Document
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17 Sep 2024	12:58 EDT	Rashid, Hani	Viewed the Document
17 Sep 2024	12:45 EDT	Devendorf, Rachel	Viewed the Document
17 Sep 2024	12:45 EDT	Devendorf, Rachel	Viewed the Document
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