# INFORMED CONSENT FORM

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| Title: | Serologic Response to a New Recombinant, Adjuvanted Herpes Zoster Vaccine in Patients with Chronic Lymphocytic Leukemia and Waldenstrom Macroglobulinemia Treated with First-Line BTK inhibitors – A Pilot Study |
| Sponsor: | University of Rochester Medical Center |
| Investigator: | Jonathan Friedberg, MD |
| NCT: | 03771157 |
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# RESEARCH SUBJECT INFORMATION AND CONSENT FORM

**TITLE**: Serologic Response to a New Recombinant, Adjuvanted Herpes Zoster Vaccine in Patients with Chronic Lymphocytic Leukemia and Waldenstrom Macroglobulinemia Treated with First-Line BTK inhibitors – A Pilot Study

**RSRB No.:** STUDY00003228

**SPONSOR:** University of Rochester Medical Center

**INVESTIGATOR:** Jonathan Friedberg, MD

**SITES:** Wilmot Cancer Institute
University of Rochester
601 Elmwood Avenue
Rochester, New York 14642

**STUDY RELATED PHONE NUMBERS:** Jonathan Friedberg, MD
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. The study staff will explain the study to you. Please 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 been diagnosed with chronic lymphocytic leukemia or Waldenstrom macroglobulinemia, are being treated with a Bruton's Tyrosine Kinase (BTK) inhibitor and are eligible to receive the Shingrix shingles vaccine.
- The purpose of this study is to measure your body's ability to generate an immune response to the Shingrix vaccine.
- Your participation in this study will last for about 14 months.
- Procedures will include a pre-vaccination blood draw, vaccination with the 2-dose series of FDA-approved Shingrix vaccine and blood draws at one month and one year following vaccination.
- There are risks from participating.

- Risks associated with blood draws include: lightheadedness, bruising at the site of needle stick, and infection.
- The most common side effects of Shingrix are:
  - Pain, redness and swelling at the injection site
  - Muscle pain
  - Tiredness
  - Headache
  - Shivering
  - Fever
  - Upset stomach
- See the "Risks of Participation" section in this 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 is that you will receive the FDA-approved shingles vaccine.
- If you do not want to take part in this study, you may be able to receive the vaccine as part of your standard care.

**Purpose of Study**

Chronic lymphocytic leukemia (CLL) and Waldenstrom macroglobulinemia (WM) are known risk factors for zoster reactivation, commonly called shingles. Although a recently FDA-approved shingles vaccine (Shingrix) is currently being offered to these patients, no study has specifically evaluated the vaccine response in patients while on treatment with single agent BTK inhibitors, the current standard therapy for this group. The purpose of this study is to evaluate the immune response, through a blood test, to the Shingrix vaccine in these patients.

**Description of Study Procedures**

If you decide to take part in this study, you will be asked to provide blood samples (25 mL; approximately 1.7 tablespoons each) before vaccination, 4 weeks after vaccination and 1 year after vaccination. On day one, blood will be drawn, and the first of two doses of the Shingrix vaccine will be administered as an injection into the muscle in your upper arm. The second dose of vaccine will be administered as an injection into your upper arm approximately 2 months after the first dose. Four weeks later you will be asked to provide a blood sample. One year after receiving the second dose of vaccine, you will be asked to provide a blood sample. Study staff may contact you around the time of vaccination to see how you are feeling.

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**

About 33 subjects will participate, all at the University of Rochester.

**Duration of the Study**

Your participation in the study will last approximately 14 months.

**Risks of Participation**
Risks associated with blood draws include: lightheadedness, bruising at the site of needle stick, and infection.

Common side effects of the Shingrix vaccine include:

- Pain, redness and swelling at the injection site
- Muscle pain
- Tiredness
- Headache
- Shivering
- Fever
- Upset stomach

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 website at any time.

The study team may be notified if you receive other health care services at URMC 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, URMC 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 is that you will receive the FDA-approved shingles vaccine, which might decrease your risk of developing shingles.

**Alternatives to Participation**
Taking part in this study is voluntary. If you choose not to participate, you may receive the vaccine as part of your standard care.

**Compensation for Injury**
If you are directly injured by the drug(s) 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 Rochester, 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**

The study will provide the Shingrix vaccine free of charge while you are participating in the study. Tests and procedures that are required solely for the study, that are not a part of your regular medical care, will also be provided at no charge. Research testing on this study includes 3 blood draws and the measurement of antibody and immune cell responses to vaccination.

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 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, PET/CT, and/or FDG/PET scans, X-rays, lung function, or cardiac testing.)
- Procedures (Including but not limited to routine items such as: bone marrow biopsies and/or aspirates, other tumor biopsies)
- Medications: other standard medications to treat your cancer (including your BTK inhibitor). 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.

**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 ensure that only approved research staff have access to your research data. 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 information and samples collected as part of this research will not be distributed or used for future research studies.

**Circumstances for Dismissal**
You may be withdrawn from the study if:

- You do not keep appointments for study visits or if you cannot complete study activities.
- You may be withdrawn from the study 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.

**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**:** Dr. Jonathan Friedberg at (585) 275-5863 (24 hours).

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.

## 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