

MARQUETTE GENERAL HEALTH SYSTEM
Regional Medical Center

CONSENT TO PARTICIPATE IN AN INVESTIGATIONAL STUDY

TITLE: Link Between U-VH chronic Lymphocytic Leukemia and Marginal Zone B Cells

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This consent form gives you detailed information about the research study which the doctor will discuss with you. The purpose of this study includes evaluation of the safety as well as the effectiveness of the investigational therapy.

AGREEMENT TO PARTICIPATE:

This signed consent is to certify my willingness to participate in this investigational (research) study.

PURPOSE OF STUDY:

The purpose of this research is to study cells from patients (such as myself) with chronic lymphocytic leukemia (CLL) to try and better identify those cell features that help predict how well a patient with CLL will do with their disease.

TREATMENT(S)/PROCEDURE(S):

I will be asked to donate approximately 7 milliliters of blood (~3 teaspoons) on up to three different occasions (at least one month apart) over period of a year. This blood will be collected by venipuncture (using a needle to obtain blood from my arm). Blood will be collected by a trained professional at Marquette General Hospital Dayton Physicians LLC. Whenever possible, blood will be collected at the same time as routine blood collection for my medical care to prevent the need for an additional needle-stick. Alternatively, samples from blood, bone marrow or lymph-nodes previously obtained from the patient will be used.

BENEFITS AND RISKS:

The potential risks associated with venipuncture are excessive bleeding, fainting, feeling light-headed, development of a hematoma (bruising caused by blood accumulating under the skin), and infection (a slight risk any time the skin is broken). There may be a need for multiple punctures to locate a vein. I understand that there is no direct benefit to me other than helping to increase understanding of the disease chronic lymphocytic leukemia.

ADDITIONAL COSTS:

There will be no additional costs to me for my participation in this study.

Institutional Funding:

Funds are provided from the study sponsor to Marquette General Hospital on a per patient basis to help with the institution's costs of participating in this study.

REMUNERATION:

I will not be paid for my participation in this study.

CONFIDENTIALITY:

The researchers will be collecting demographic information about me (name, age, sex) as well as laboratory information about the cells in my blood. All this information will be kept locked at Marquette General Hospital to maintain confidentiality, and no identifiable information will be sent with my sample for testing.

WHOM TO CONTACT:

In the event that physical injury occurs as a result of this research, facilities for treatment of injury will be available; however, you will not automatically be provided with reimbursement for medical care or other compensation. For more information concerning the research and research-related risks or injuries, you can notify Dr. Aaron Scholnik, or his/her associates, who may be reached by phoning the office at (906) 225-3922 or Osvaldo Lopez, Ph.D. at 937-775-4627. During the evenings, weekends, or holidays you may phone Marquette General Health System at (906) 228-9440, and request to speak with the medical oncologist on call. You can also call the Patient Advocate at Marquette General Health System at (906) 228-3183, if you have any questions, comments, or concerns about the study or your rights as a research subject.

VOLUNTARY CONSENT:

I understand that I am free to refuse to participate in this study or to withdraw at any time. My decision to participate or to not participate will not adversely affect my care at this institution or cause a loss of benefits to which I might otherwise be entitled.

My signature below means that I have freely agreed to participate in this investigational study.

SIGNATURE/DATE LINES:

_____	_____
Name/Signature of Participant	(Date)
_____	_____
(Physician/PI)	(Date)