



# Heartland Cancer Research

An NCI-Designated Community  
Clinical Oncology Program

APPROVED BY THE  
MISSOURI BAPTIST MEDICAL CENTER  
INSTITUTIONAL REVIEW BOARD

DATE OF APPROVAL: \_\_\_\_\_ DEC 14 2011  
CONSENT FORM EXPIRES : \_\_\_\_\_ DEC 13 2012

## INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

**TITLE OF STUDY: E1908 - A Phase II Randomized Trial Comparing Standard and Low Dose Rituximab: Initial Treatment of Progressive Chronic Lymphocytic Leukemia in Elderly Patients using Alemtuzumab, and Rituximab**

**PRINCIPAL INVESTIGATOR: Alan P. Lyss, M.D.**

**PARTICIPANT NAME:** \_\_\_\_\_

This is a clinical trial, a type of research study. Your doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your doctor for more explanation.

You are being asked to take part in this study because you have chronic lymphocytic leukemia (CLL) that now requires treatment.

### WHY IS THIS STUDY BEING DONE?

The purpose of this study is to find out what effects, good and/or bad, treatment with the combination of alemtuzumab and rituximab has on you and your CLL. In addition, we will test if lower doses of rituximab given three times a week could be more effective than the standard larger dose given once a week.

The drugs used in this study are approved for use in cancers of lymphocytes such as CLL. However, the combination of drugs is experimental and has not been approved by the FDA for use in CLL.

### HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 90 people will take part in this study.

### **WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?**

All testing and treatment will be done in an outpatient setting.

You will get up to 3 cycles of treatment while on this study. The first cycle of treatment is 32 days and the subsequent two cycles are each 28 days long. After 2 cycles of treatment you will have tests to see how your disease has responded to treatment. If your disease has completely responded, treatment will be stopped. If your disease has remained the same or partially responded to treatment you will get a third cycle of treatment.

### **BEFORE YOU BEGIN THE STUDY**

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your doctor.

- Routine exams and procedures:
  - Physical exam
  - CT scan
  - Bone marrow biopsy and aspirate
- Routine blood tests

### **Central Review**

Samples of your blood (two teaspoons) or bone marrow (less than one teaspoon) will be sent to a central laboratory for analysis during preregistration. The results of the analysis will be used to determine your treatment assignment.

### DURING THE STUDY

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures. They are part of regular cancer care.

|  |   |
|--|---|
| Every week during treatment              | <ul style="list-style-type: none"> <li>• Routine exams and procedures (i.e. physical exam)</li> <li>• Routine blood tests</li> </ul>  |
| End of each Cycle                        | • Routine exams   |
| After 2 <sup>nd</sup> cycle of treatment | <ul style="list-style-type: none"> <li>• Routine exams and procedures (i.e. physical exam, CT scan, bone marrow biopsy and aspirate)</li> <li>• Routine blood tests</li> </ul>  |
| Monthly after treatment                  | <ul style="list-style-type: none"> <li>• Routine exams and procedures (i.e. physical exam, CT scan at 2 month visit only, bone marrow biopsy and aspirate at 2 month visit only)</li> <li>• Bone marrow biopsy and aspirate (only at Month 2 visit)</li> <li>• Routine blood tests</li> </ul> |
| 9 and 12 months after treatment          | <ul style="list-style-type: none"> <li>• Routine exams and procedures (i.e. physical exam)</li> <li>• Routine blood tests</li> </ul>  |

### Central Review

Samples of your bone marrow biopsy will be sent to a central laboratory for review after you have completed two cycles of therapy if you are in clinical complete response to determine if you should receive another cycle of treatment.

Samples of your bone marrow biopsy will be sent to a central laboratory for review two months after completion of therapy if your disease has responded to treatment.

Pictures of your chromosomes (karyotypes) will be sent to a central laboratory to be examined by central reviewers at baseline and after two cycles of therapy.

You will be "randomized" into one of the study groups described in the study chart. Randomization means that you are put into a group by chance. A computer program will place you in one of the study groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in any group.

### Study Chart

Treatment will be given according to the following schedule:

If you are in Arm A:

| Cycle 1        |  |   |
|----------------|--|---|
| Drug           | How given  | Treatment days  |
| Alemtuzumab    | Subcutaneous injection (injected under the skin with a needle) | 1, 2, 3, 6, 8, 10, 13, 15, 17, 20, 22, 24, 27, 29, 31 |
| Rituximab      | Standard dose IV (by a needle into a vein)                     | 8, 15, 22, 29   |
| Cycles 2 and 3 |  |   |
| Alemtuzumab    | Subcutaneous injection (injected under the skin with a needle) | 1, 3, 5, 8, 10, 12, 15, 17, 19, 22, 24, 26            |
| Rituximab      | Standard dose IV (by a needle into a vein)                     | 3, 10, 17, 24   |

You will also receive other medications prior to and during treatment to help control side effects.

If you are in Arm B:

| Cycle 1        |  |   |
|----------------|--|---|
| Drug           | How given  | Treatment days  |
| Alemtuzumab    | Subcutaneous injection (injected under the skin with a needle) | 1, 2, 3, 6, 8, 10, 13, 15, 17, 20, 22, 24, 27, 29, 31 |
| Rituximab      | Low dose IV (by a needle into a vein)                          | 6, 8, 10, 13, 15, 17, 20, 22, 24, 27, 29, 31          |
| Cycles 2 and 3 |  |   |
| Alemtuzumab    | Subcutaneous injection (injected under the skin with a needle) | 1, 3, 5, 8, 10, 12, 15, 17, 19, 22, 24, 26            |
| Rituximab      | Low dose IV (by a needle into a vein)                          | 1, 3, 5, 8, 10, 12, 15, 17, 19, 22, 24, 26            |

You will also receive other medications prior to and during treatment to help control side effects.

### **WHEN I AM FINISHED TAKING DRUGS**

After you have completed therapy you will continue to be monitored for possible complications of treatment and for your response to treatment. If you did not achieve a complete response to treatment after 2 cycles of therapy, you will be re-evaluated for your response to treatment 2 months after completing the third cycle of therapy. This evaluation could include a bone marrow examination and CT scan if appropriate. You will also be monitored monthly for 6 months after completion of therapy for potential complications of treatment. These visits will include routine blood tests. You will then be evaluated at 9 and 12 months after completion of therapy by clinical examination and blood tests to determine if your CLL has changed. All this routine testing is standard of care for patients with CLL treated with these drugs. One year after completion of therapy, you will return to routine follow up for your CLL with your health care provider.

### **HOW LONG WILL I BE IN THE STUDY?**

You will be asked to take alemtuzumab and rituximab for approximately 3 months, depending on your response. After you are finished taking drugs, the doctor will ask you to visit the office for follow-up exams for at least 12 months. We would like to keep track of your medical condition for the next 5 years. We would like to do this by calling you on the telephone once a year to see how you are doing. Keeping in touch with you and checking on your condition every year helps us look at the long-term effects of the study

### **CAN I STOP BEING IN THE STUDY?**

Yes. You can decide to stop at any time. Tell the doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the doctor if you are thinking about stopping so any risks from the drugs can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

### **WHAT SIDE EFFECTS OR RISKS CAN I EXPECT FROM BEING IN THE STUDY?**

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop taking the *drugs*. In some cases, side effects can be serious, long lasting, or may never go away. There also is a risk of death from complications of use of these drugs.

You should talk to your doctor about any side effects that you have while taking part in the study.

**Alemtuzumab**

**Risks and side effects related to the drugs include those which are:**

**Likely:**

- Nausea or the urge to vomit
- Vomiting
- Chills
- Fatigue or tiredness
- Fever
- Lowered white blood cell count (may make you more likely to get infections)
- Lowered platelet count that might interfere with clotting (may make you more likely to bruise or bleed)
- Lowered red blood cell count (may cause anemia and make you feel weak and tired)

**Less Likely:**

- Abnormal blood clotting and/or bleeding
- Fever associated with dangerously low levels of a type of white blood cell (neutrophils)
- Irregular heartbeat
- Heart attack caused by a blockage of a blood vessel supplying part of the heart
- Fast heartbeat
- Abnormal levels of thyroid gland hormone (whether high or low that can cause fatigue, weight loss)
- Belly pain
- Constipation
- Diarrhea
- Heartburn
- Irritation or sores in the lining of the mouth
- Irritation or sores in the lining of the small bowel
- Swelling of the arms and/or legs
- Flu-type symptoms (including body aches, fever, chills, tiredness)
- Inflammation (swelling and redness) or damage to the tissue surrounding where a drug was injected
- Chest pain not heart-related
- Allergic reaction to alemtuzumab
- Severe immune reaction causing destruction of a person's own healthy body tissue by their own immune system
- Potentially life-threatening condition during a drug infusion which may cause low blood pressure, rash, fever, chills, difficulty breathing, rapid heartbeat, nausea, and kidney damage

- Allergic reaction to other medications, injected proteins, or antisera (blood product) used to treat certain medical conditions (such as an infectious or poisonous substance)
- Infection
- Reversible changes in blood tests for liver function that may indicate damage to the liver
- Loss of appetite
- Decreased levels of a blood protein called albumin that can cause swelling
- Inflammation (swelling and redness) in a joint (arthritis)
- Back pain
- Muscle weakness of the whole body
- Muscle pain
- Dizziness (or sensation of lightheadedness, unsteadiness, giddiness, spinning or rocking)
- Taste changes
- Headache or head pain
- Inflammation (swelling and redness) or degeneration of the peripheral nerves (those nerves outside of brain and spinal cord) causing numbness, tingling, burning
- Difficulty sleeping or falling asleep
- Stuffy or runny nose, sneezing
- Sudden constriction of the muscles in the walls of the bronchioles (small airways of the lung) that causes wheezing and or shortness of breath
- Cough
- Shortness of breath
- Decrease in the oxygen supply to a tissue
- Inflammation (swelling and redness) of the lungs that can cause shortness of breath
- Abnormal build up of fluid in the lungs
- Abnormal, high-pitched, musical breathing sound caused by a blockage in the throat or voice box
- Itching
- Area of bleeding within the skin causing a reddish purple discoloration
- Acne; pimples
- Hives
- Sudden reddening of the face and/or neck
- High blood pressure
- Low blood pressure

**Rare but Serious:**

- A condition in which bone marrow (the tissue that is contained within bones) stops producing blood cells
- Destruction of red blood cells
- Decrease in heart's ability to pump blood

## **Rituximab**

### **Likely:**

- Chills
- Fever
- Reaction that can occur during or following infusion of the drug. The reaction may include fever, chills, rash, low blood pressure, and difficulty breathing.
- Lowered white blood cell count (may make you more likely to get infections)

### **Less Likely:**

- Lowered red blood cell count (may cause anemia and make you feel weak and tired)
- Fever associated with dangerously low levels of a type of white blood cell (neutrophils)
- Heart attack caused by a blockage of a blood vessel supplying part of the heart
- Fast heartbeat
- Belly pain
- Diarrhea
- Nausea or the urge to vomit
- Vomiting
- Swelling of the arms and/or legs
- Fatigue or tiredness
- Pain
- Allergic reaction by your body to the drug product that can occur immediately or may be delayed. The reaction may include hives, low blood pressure, wheezing, swelling of the throat, and difficulty breathing.
- Allergic reaction to other medications, injected proteins, or antisera (blood product) used to treat certain medical conditions (such as an infectious or poisonous substance)
- Infection
- Awakening of viruses which have been latent/dormant
- Infection in HIV positive patients
- Lowered platelet count that might interfere with clotting (may make you more likely to bruise or bleed)
- Decrease in the total number of white blood cells (leukocytes)
- Increased blood sugar level
- Decreased blood level of calcium
- Decreased blood level of potassium
- Joint pain
- Back pain
- Muscle pain
- Pain in the area of the tumor
- Dizziness (or sensation of lightheadedness, unsteadiness, or giddiness)
- Headache or head pain

- Abnormal drowsiness or sluggishness, an unusual lack of energy
- Convulsion or seizure
- Sudden or traumatic injury to the kidney
- Stuffy or runny nose, sneezing
- Sudden constriction of the small airways of the lung that can cause wheezing and shortness of breath
- Cough
- Shortness of breath
- Decrease in the oxygen supply to a tissue
- Inflammation of the lungs that may cause difficulty breathing and can be life-threatening
- Sore throat
- Excess sweating
- Itching
- Skin rash
- Swelling of body tissue underneath the skin
- Hives
- Sudden reddening of the face and/or neck
- High blood pressure
- Low blood pressure

**Rare but Serious:**

- Serious, life-threatening allergic reaction requiring immediate medical treatment by your doctor. The reaction may include extremely low blood pressure, swelling of the throat, difficulty breathing, and loss of consciousness.
- Group of signs and symptoms due to rapid breakdown of tumor that can occur after treatment of cancer has started that causes increased levels of blood potassium, uric acid, and phosphate, decreased levels of blood calcium, and kidney failure
- Disease affecting brain tissue, caused by a virus
- Severe potentially life-threatening damage to the lungs which can lead to fluid in the lungs
- Severe reaction of the skin and gut lining that may include rash and shedding or death of tissue
- Potentially life-threatening condition affecting less than 10% of the skin in which cell death causes the epidermis (outer layer) to separate from the dermis (middle layer)
- Life-threatening skin condition in which cell death causes the epidermis (outer layer of skin) to separate from the dermis (middle layer of skin). The greater the area of skin involved, the greater the seriousness of the condition.

It is not known whether rituximab can cause fetal harm when given to pregnant woman or whether it affects the ability to have children. However, as IgG immunoglobulins (antibodies) are known to cross the placental barrier, rituximab may cause harm to the fetus' immune system. For these reasons, rituximab should not be given to pregnant woman unless the possible

benefit outweighs the potential risk. Women of child bearing age should use effective contraceptive methods during and for up to 12 months after treatment with rituximab. The use of rituximab during breast feeding has not been studied. It is not known whether rituximab is present in human breast milk. It should not be given to nursing mothers.

**Reproductive risks:** You should not become pregnant or father a baby while on this study because the drugs in this study can affect a fetus. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while on this study. Check with your doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study.

For more information about risks and side effects, ask your doctor.

#### **ARE THERE BENEFITS TO TAKING PART IN THE STUDY?**

Taking part in this study may or may not make your health better. While doctors hope the drugs will be more useful against cancer compared to the usual treatment, there is no proof of this yet. We do know that the information from this study will help doctors learn more about the drugs as a treatment for cancer. This information could help future cancer patients.

#### **WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?**

Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting no treatment

Talk to your doctor about your choices before you decide if you will take part in this study.

#### **WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?**

Protected health information (PHI) is health information that identifies you. This information is protected by Federal law under the Health Insurance Portability and Accountability Act (HIPAA). Your rights regarding your health information will be further explained to you in a separate consent form.

The Eastern Cooperative Oncology Group (ECOG) is conducting this study. ECOG is a cancer research group that conducts studies for the National Cancer Institute. Your doctor is a member of ECOG or another group that is participating in this study. To help protect your privacy, ECOG has obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS).

With this Certificate, ECOG cannot be forced (for example, by court subpoena) to disclose information that may identify you in any federal, state or local civil, criminal, administrative, legislative or other proceeding. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

You should know that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about you or your involvement in this research. If an insurer or employer learns about your participation and obtains your consent to receive research information, then ECOG may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your privacy.

You should also understand that your doctor and ECOG may take steps, including reporting to authorities, to prevent you from seriously harming yourself or others.

Finally, the Certificate does not prevent the review of your research records under some circumstances by certain organizations for an internal program audit or evaluation. Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as:

- Eastern Cooperative Oncology Group (ECOG)
- National Cancer Institute (NCI)
- Food and Drug Administration (FDA)
- Other regulatory agencies and/or their designated representatives
- Central laboratories, banks and/or reviewers
- CTSU – Cancer Trials Support Unit
- Missouri Baptist Medical Center Staff
- Missouri Baptist Institutional Review Board (a group of people who review the research study to protect your rights)

#### **WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?**

You and/or your health plan/ insurance company will need to pay for the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

You will not be charged for any optional research studies.

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

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's Web site at:

<http://cancer.gov/clinicaltrials/understanding/insurance-coverage>

You can print a copy of the "Clinical Trials and Insurance Coverage" information from this Web site.

Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

**WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?**

It is important that you tell your doctor if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her at his usual office phone number.

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

**WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?**

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

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

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

**WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?**

You can talk to your doctor about any questions or concerns you have about this study. Contact your doctor at his/her usual phone number.

For questions about your rights while taking part in this study, call the Missouri Baptist Medical Center Institutional Review Board (a group of people who review the research to protect your rights) at 314-996-5186.

**Please note: This section of the informed consent form is about additional research studies that are being done with people who are taking part in the main study. You may take part in these additional studies if you want to. You can still be a part of the main study even if you say 'no' to taking part in any of these additional studies.**

#### **ABOUT USING SPECIMENS FOR RESEARCH**

Please read this form and ask about anything that is not clear to you. This is part of the **informed consent** process for research. This is to inform you of the possible risks, benefits, and limits of giving your samples for research.

You are being asked to give some of your samples (called **specimens**) and related information to be used in research studies defined in the protocol and to be stored (banked) for future research. This may help researchers learn more about how to prevent, find and treat cancer and other diseases.

The choice to have your samples used for research is up to you. No matter what you decide, it will not affect your medical care.

Below is some general information you should know before agreeing to allow the use of your specimens for research. After the general information there are descriptions of the research projects. Each project is described separately, including the types of samples requested and how they are collected. Each description is followed by questions concerning your participation in the project. Your samples will be used only for the projects in which you agree to participate.

#### **What are samples and where are they stored?**

A sample is any material taken from your body such as tissue, blood, urine and other fluids.

If you agree, your samples will be sent to laboratories to be used in research or will be stored for research in a Cooperative Group bank. These banks are supported by the National Cancer Institute. Cooperative Group banks contain samples and information. Your samples are kept along with those from other people in the banks. Researchers then ask for samples from the banks to study them.

#### **What information will be collected?**

When your samples are sent to any research laboratory or bank, some personal information will be sent with the samples. Any personal information sent with the samples is not given to other researchers. The personal information is used only by the laboratory or bank to identify your samples. Your privacy will be protected to the fullest extent possible. This will be discussed later in the section "How will information related to my samples be protected?"

Examples of other information that might be used for research include:

- Dates of medical procedures
- Any diagnosis and stage of your disease
- Your age and race

- Medical and family history
- Treatments you had
- How you responded to treatments

### **What will happen to my samples if I agree to give them for research?**

If you agree to provide samples for the planned laboratory research studies, your samples will be sent to researchers who will study them to find answers to specific questions. These researchers may receive some personal identifying information but it will be used only to identify your samples.

If you agree to let your samples be kept for future research (research not yet defined), your samples will be stored in a Cooperative Group bank. The samples will be kept until they are used up or destroyed. The samples are given a code to protect your privacy before they are used. Any related information given to researchers will also be coded. Researchers will receive the code instead of any information that might directly identify you.

You or your doctor will not be given reports or other information about the research that uses your samples. This information will not be put into your health record. Results may be used for future research.

You will not be named or identified by other personal information if any results are published. Most publications contain results from many patients.

Your samples and related information will be used only for research and will not be sold. It is possible that research may help to create new products or treatments. If this should happen, you will not be paid.

Coded data from some research studies that use samples could be put into secure Internet databases that can be shared by other approved researchers. This could include genetic data. Current safety rules are followed to safeguard your privacy. Your name or contact information will not be put in the database.

### **What kind of research will be done with my samples?**

Many types of research use normal or diseased (**cancerous**) samples. Researchers can study proteins, RNA and DNA (genes). The study of genes (DNA) is often called **genetic research**.

For example, your samples may be looked at:

- To see if a trait is passed down in families from one generation to the next (**inherited**). This type of research may help to explain why some cancers run in families or why some people have side effects from treatment while others do not. This is often studied through blood cells and DNA (**genes**).
- To learn about changes in the body that happen after you were born (**non-inherited**). For example, being in the sun too much can cause changes in cells that lead to skin cancer.

### **Will it help me if I give my samples for research?**

Using your samples for research will probably not help you. We do hope the research results will help people in the future. The best way to prevent, find or treat cancer and other diseases is by studying human samples and data.

### **What are the risks of giving my samples for research?**

There is a risk that your information could be misused. The chance of this happening is very small. We have many protections in place to lower this risk. See the next section, "How will the information related to your samples be protected?" Your privacy will be protected to the fullest extent possible.

There can be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a research study. Even though your genes are unique, you share some of the same genes with your blood relatives. Very rarely health or genetic information could be misused by employers, insurance companies, and others. For example, life insurance companies may charge a higher rate based on this information.

Some states have laws to protect against genetic. A new federal law called the Genetic Information Non-Discrimination Act, or GINA is in effect. This law helps to lower the risk of health insurance or employment discrimination. The law does not include other types of misuse by life insurance or long term care insurance. To learn more about the GINA Law, please check the Internet or ask the study staff.

Although we are not able to know all of the risks from taking part in research on inherited traits, we believe that the risks to you and your family are very low, because research results will not be returned to you or your doctor.

### **How will information related to my samples be protected?**

We have many ways to protect the information related to your samples:

Your samples and information receive a unique code. Researchers only receive coded samples and information, and will not be able to link the code to you. Only approved people in the Eastern Cooperative Oncology Group can match you to the code on your samples and related information.

Strict security safeguards are in place to reduce the chance of misuse or unplanned release of information. Steps we take include password protected access to databases and restricted access to freezers or rooms that contain samples.

Before samples are given to researchers, studies are reviewed for the quality of the science and for patient protection. Records from research studies can be reviewed by the Cooperative Group, by the sponsor, and by government agencies. This is to make sure the research follows the rules of the Cooperative Group and state or federal laws.

Research results will not be returned to you or your doctor. If research results are published, your name and other personal information will not be given.

ECOG also has a Certificate of Confidentiality from the U.S. Department of Health and Human Services. The Certificate protects against the forced release of personal information from the Cooperative Group bank or database.

What this means is that ECOG cannot be forced to disclose your identity to any third party. It is possible that for some legal proceedings, the Certificate of Confidentiality could be over-ridden by a court of law.

### **Making your choice**

The choice to take part is up to you. You may choose not to let us store and use your samples. If you decide not to let us store and use your samples, you will still receive the same medical care and you may still participate in the treatment part of this clinical trial. You may also take part in other research studies.

If you decide that your samples can be kept, you may change your mind at any time. Contact the study staff at your hospital and let them know that you do not want your samples used for research at 314-996-5442. Then, any sample that remains in the bank will no longer be used. Samples that have already been given to or used by researchers cannot be returned or destroyed.

Please read the research study descriptions below, review the questions carefully and circle "Yes" or "No". **If you have any questions, please talk to your doctor or nurse.**

### **LABORATORY RESEARCH STUDIES**

This study includes one or more laboratory tests that will analyze small samples of blood and bone marrow. The bone marrow samples will be collected during your routine biopsies performed during your therapy. About one teaspoon of bone marrow will be collected after you complete two cycles of therapy. The blood samples will be collected using a needle to draw some blood out of a vein.

The blood will be collected:

- prior to treatment at baseline(11 teaspoons),
- after two cycles of therapy (2 teaspoons),
- six months after therapy (7 teaspoons),
- 12 months after therapy (7 teaspoons).
- About seven (7) teaspoons of blood will also be collected during your first week of therapy. An additional blood sample (1 teaspoon) will be collected after two cycles of therapy if you are in complete clinical response and two months after therapy (1 teaspoon) if you have responded to treatment.

The specimens will be sent to laboratories, where tests will be performed. Researchers will perform these tests in order to understand the mechanisms by which alemtuzumab and rituximab kill CLL cells and how these drugs affect the function of the immune system.

Please read the question below and circle "Yes" or "No".

**I agree to participate in the laboratory research studies that are being done as part of this clinical trial.**

**Yes    No**

### USING SPECIMENS FOR FUTURE RESEARCH

We would like to keep some of your specimens for research that is not yet defined (future research).

If you participate in the laboratory research studies associated with this protocol, this means any specimens left over from the laboratory studies will be stored. Additionally, any leftover specimens collected as part of the central reviews will also be stored.

Although most future research studies will focus on cancer, some research projects may also include other diseases, such as heart disease, diabetes or Alzheimer's disease.

As indicated above, the specimens will only be given to researchers approved by scientific reviewers appointed by the Eastern Cooperative Oncology Group. Any research done on the specimens must also be reviewed by the researcher's Institutional Review Board.

Please read the questions below carefully and circle "Yes" or "No".

**May your coded samples and related coded information be kept for use in research to learn about, prevent, find or treat cancer? This may also include research on inherited traits (genes passed on in families).**

Yes      No

**May your coded samples and related coded information be kept for use in research to learn about, prevent, find or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease). This may also include research on inherited traits (genes passed on in families).**

Yes      No

### PERMISSION TO CONTACT YOU IN THE FUTURE

We request your permission to contact you in the future about taking part in more research studies. If you agree and we decide to contact you in the future, we will first contact your doctor or some one at your hospital. They will tell you why we would like to contact you and, if you agree, they will send us your contact information. We will not attempt any direct contact without obtaining this second permission from you.

**Someone from my hospital or the Eastern Cooperative Oncology Group may contact me in the future to ask me to take part in more research.**

Yes      No

**WHERE CAN I GET MORE INFORMATION?**

You may call the National Cancer Institute's Cancer Information Service at:  
1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

You may also visit the NCI Web site at <http://cancer.gov/>

For NCI's clinical trials information, go to: <http://cancer.gov/clinicaltrials/>

For NCI's general information about cancer, go to <http://cancer.gov/cancerinfo/>

**This study has been reviewed by the Missouri Baptist Medical Center Institutional Review Board (IRB). The Missouri Baptist Medical Center IRB is a Federally recognized, administrative group established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted at Missouri Baptist Medical Center. If you have any questions or concerns regarding this study, or if any problems arise, you may call the Principal Investigator at 314-996-5569. You may also ask questions or state concerns regarding your rights as a research subject to Dr. David Striker, Chairman of the Institutional Review Board, Telephone: (314) 996-5186.**

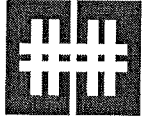
I have read this consent form and have been given the opportunity to ask questions. I will also be given a signed copy of this consent form for my records. I hereby consent to my participation in the research described above.

\_\_\_\_\_  
Participant's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Investigator's Signature

\_\_\_\_\_  
Date



# Heartland Cancer Research

An NCI-Designated Community  
Clinical Oncology Program

## **Authorization to Use and Disclose Personal Health Information for Study:**

### **E1908 – A Phase II Randomized Trial Comparing Standard and Low Dose Rituximab: Initial Treatment of Progressive Chronic Lymphocytic Leukemia in Elderly Patients using Alemtuzumab, Rituximab**

A federal government rule has been issued to protect the privacy rights of patients. This rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This rule is designed to protect the confidentiality of your personal health information. Your personal health information is information about you that could be used to find out who you are. For this research study, this includes information in your existing medical records needed for this study and new information created or collected during the study.

This Authorization explains how your personal health information will be used and who it will be given to (“disclosed”) for this research study. It also describes your privacy rights, including your right to see your personal health information.

By signing this Authorization form, you will give permission (“authorization”) for the uses and disclosures of your personal health information that are described in this Authorization. If you do not want to allow these uses and disclosures, you should not participate in this study.

If you agree to participate in the research study, your personal health information will be used and disclosed in the following ways:

- The study doctor and staff (also known as the research team) will use your medical records and information created or collected during the study to conduct the study.
- The research team will send your study-related health information (“study data”) to the sponsor of the study and its representatives (“sponsor”). If the sponsor conducts business related to clinical research in multiple countries around the world, this may involve sending your study data outside of the United States. Other countries may have privacy laws that do not provide the same protections as the laws in this country. However, the sponsor will respect the terms of this Authorization in all countries.

- The study data sent by the research team to the sponsor generally does not include your name, address, social security number, or other information that *directly* identifies you. Instead, the research team often assigns a code number to the study data, which may include your initials or other similar information. Some study data used or disclosed under this Authorization may contain other information that could be used (perhaps in combination with other information) to identify you (eg, date of birth). If you have questions about the specific health information that will be used or disclosed pursuant to this Authorization, you should ask the study doctor.
- The research team and sponsor will use the study data for research purposes to support the scientific objectives described in the consent document and the process of getting regulatory approvals for its drugs, devices or other products.
- The sponsor or research team may add your study data to data from other studies in research databases so that it can study better measures of safety and effectiveness, study other therapies for patients, develop a better understanding of diseases, or improve the design of future clinical trials.
- Your study data, either alone or combined with data from other studies, may be shared with regulatory authorities in the United States and other countries, research teams at other institutions participating in the study, central study cooperative or monitoring groups, and the review board overseeing this study.
- Study data that does not directly identify you may be published in medical journals or shared with others as part of scientific discussions or training.
- Your original medical records, which may contain information that directly identifies you, may be reviewed by the sponsor, the ethical review board overseeing this study, and regulatory authorities in the United States and other countries. The purpose of these reviews is to assure the quality of the study conduct and the study data, or for other uses authorized by law. Portions of your medical record may be stored by the research team in the research record, as well.
- The sponsor may work with business partners in drug development. The sponsor may share your study data with these business partners, but only if the business partners need the information as a part of this work with the sponsor, and only if the business partners agree to protect your study data in the same way as the sponsor.
- Your medical records and study data may be held and processed on computers.
- Your personal health information or study data may be used or disclosed in any other manner or to any other person or organization referenced in the Informed Consent document to which this Authorization is attached or related.

Your personal health information may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team to these other parties.

You have the right to see and copy your personal health information related to the research study for as long as this information is held by the study doctor or research institution. However, to ensure the scientific integrity of the study, you agree that you will not be able to access or review such study information until after the study has been completed, when your access rights will be re-stored.

You may cancel your authorization at any time by providing written notice to the study doctor. If you cancel your authorization, you will no longer be able to participate in the study. However, if you decide to cancel your authorization and withdraw from the study, you will not be penalized or lose any benefits to which you are otherwise entitled.

If you cancel your authorization, the research team will no longer use or disclose your personal health information in connection with this study, unless the research team needs to use or disclose some of your personal health information to preserve the scientific integrity of the study or for other purposes for which the research team has relied upon your original authorization (e.g., to be paid for services). The sponsor, oversight boards and regulatory agencies may still use study data that was collected before you canceled your authorization for the original purpose(s) of those disclosures.

Your consent for the uses and disclosures described in this Authorization does not have an expiration date.

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Signature of Participant

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Date (by Participant)

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Participant Name (Print or Type)

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Participant Initials and  
Number (if applicable):

Complete ONLY if Authorization is signed by a legal representative of the Participant

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Signature of Legal Representative

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Date (by Legal  
Representative)

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Legal Representative Name (Print or Type)

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If signed by Legal Representative, description of  
relationship to patient or other basis for legal authority