Wake Forest™
School of Medicine

Comprehensive Cancer Center of Wake Forest University

INVESTIGATING THE PROGNOSTIC IMPORTANCE OF BIOELECTRICAL IMPEDANCE ANALYSIS (BIA) IN ADULTS TREATED FOR NEWLY DIAGNOSED ACUTE LEUKEMIA

Informed Consent Form to Participate in Research
Timothy Pardee, M.D., Principal Investigator

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have a newly diagnosed acute leukemia. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family. Please note: If you have a pacemaker or a defibrillator, you should not participate in this study. Additionally, if you are pregnant, you should not participate in this study.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test if the way a person's body conducts electricity can predict how well people with acute leukemia tolerate their chemotherapy.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 102 people here at WFUBMC will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

Bioelectrical impedance analysis (BIA) uses a small handheld device (similar to body fat analysis instruments used in weight loss centers) to measure how your body conducts a small electrical current. For BIA, two electrodes will be attached with a sticky pad to the outside of your hand and also two on the outside of your foot. The device will send a small electric current from your hand to your leg and measure the electrical resistance. The current is very small and you will not be able to feel it. It is similar to having an electrocardiogram or EKG. The procedure takes about two to five minutes.

In addition to the BIA, we would like to follow your progress for the next two years.

Additional Evaluations and Procedures:

There are no special evaluations or procedures required other than the measurements as

described above.

HOW LONG WILL I BE IN THE STUDY?

If you agree to participate you will have a BIA within the first 3 days of receiving chemotherapy.

If you have acute myeloid leukemia (AML) you will have a second BIA in the hospital, within 2 days of your second bone marrow biopsy.

After you are discharged home there will be no additional measurements taken but you will be followed by the study staff for a total of 2 years.

You can stop participating at any time.

WHAT ARE THE RISKS OF THE STUDY?

Taking part in this study involves some risks and possible discomforts. There are no known side effects to having the measurement taken. The measurements are painless but you may have an allergic reaction or skin irritation to the adhesive on the electrode.

If you have a pacemaker or a defibrillator or if you are pregnant, you should not participate in this study.

If you have questions about risks and side effects, ask your study doctor. ***You should talk to your study doctor about any side effects that you have while taking part in this study.*** The study doctor will take steps to try to treat any side effects, if they appear.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There are no direct benefits to participating in the study. The information obtained from this study may help doctors better understand how BIA can be used to predict tolerability and response to chemotherapy. This may eventually be helpful to future leukemia patients.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment for your condition and your participation will in no way alter your planned therapy.

WHAT ABOUT THE USE, DISCLOSURE AND CONFIDENTIALITY OF HEALTH INFORMATION?

By taking part in this research study, your personal health information, as well as information that directly identifies you, may be used and disclosed. Information that identifies you includes, but is not limited to, such things as your name, address, telephone number, and date of birth. Your personal health information includes all information about you which is collected or created during the study for research purposes. It also includes your personal health information that is related to this study and that is maintained in your medical records at this institution and at other places such as other hospitals and clinics where you may have received medical care. Examples of your personal health information include your health history, your family health

history, how you respond to study activities or procedures, laboratory and other test results, medical images, photographs/videotapes/audiotapes and information from study visits, phone calls, surveys, and physical examinations.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

If this research study involves the treatment or diagnosis of a medical condition, then information collected or created as part of the study may be placed in your medical record and discussed with individuals caring for you who are not part of the study. This will help in providing you with appropriate medical care. In addition, all or part of your research related health information may be used or disclosed for treatment, payment, or healthcare operations purposes related to providing you with medical care.

When you sign this consent and authorization form you authorize or give permission for the use of your health information as described in the consent form. You can revoke or take away your authorization to use and disclose your health information at any time. You do this by sending a written notice to the investigator in charge of the study at the following address:

Timothy Pardee, M.D.
[redacted]

If you withdraw your authorization you will not be able to be in this study. If you withdraw your authorization, no new health information that identifies you will be gathered after that date. Your health information that has already been gathered may still be used and disclosed to others. This would be done if it were necessary for the research to be reliable. You will not have access to

your health information that is included in the research study records until the end of the study.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

This authorization is valid for six years or five years after the completion of the study, whichever is longer.

WHAT ARE THE COSTS?

There are no costs to you for having the BIA done.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study. The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur. Parking validation will be provided for all study-related visits.

WHO IS SPONSORING THIS STUDY?

Wake Forest University Health is sponsoring this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied. Other funds to support the costs of this study will come from the Comprehensive Cancer Center at Wake Forest University.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Timothy Pardee, M.D., at [redacted].

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the

study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best interest; you do not follow the study rules; the study is stopped; you do not later consent to any future changes that may be made in the study plan; you become pregnant; or for any other reason.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, Timothy Pardee, M.D., at [redacted].(Days/Nights/Weekends).

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm