Novel 3D Hematological Malignancy Organoid Platform to Study Disease
Biology and Perform Chemosensitivity Assays for Patient-specific Care *WFBCCC26A19*: Novel 3D Hematological Malignancy Organoid to Study Disease Biology and Chemosensitivity
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Hematology and Oncology Service, Department of Internal Medicine

Novel 3D Hematological Malignancy Organoid Platform to Study Disease Biology and Perform Chemosensitivity Assays for Patient-specific Care

Informed Consent Form to Participate in Research
Timothy Pardee, M.D., Ph.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 been scheduled for a bone marrow biopsy. 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.

WHY IS THIS STUDY BEING DONE?

The purpose of this research is to have a better understanding of how cancer cells from hematological malignancies (cancer that involves bone marrow, blood, and lymph nodes) interact with other elements in the bone marrow that keep it alive. The model created with your sample may help us understand how chemotherapy works in cancer and try to find what chemotherapies work better for your type of tumor. It may also help us find new treatments by testing new drugs with the sample.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

There will be at least 210 and a maximum of approximately 360 people at WFBH that will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

In this study we will collect two tubes of blood, and a small amount of bone marrow aspirate from you during your scheduled bone marrow biopsy recommended by your physician. Blood and the bone marrow aspirate collected are considered part of your standard of care to help with treatment of your cancer. An additional tube of bone marrow aspirate will be collected for the study. When you get a routine blood sample drawn in preparation for the marrow biopsy, 2 additional tubes of blood will be obtained for the study.

Any leftover samples that are not used by the Pathology Department to complete the tests ordered by your doctor will be collected for the study so the sample is not wasted. These remaining samples will be outsourced to labs to run tests on equipment that is not available here at Wake Forest Baptist Health.

If you have had chemotherapy prior to this procedure or require chemotherapy after, we would like to get information from your medical record to compare your response you had to treatment and compare it with the response of the organoid models. We will test other chemotherapy treatments in the organoids and study how the tumors respond to it. We will also obtain information about your disease from your medical record and the Advanced Tumor Bank database to learn more about your cancer.

The results of this study will not in any way determine your course of treatment. The results of these experiments are for research purposes only. If you take part in this study, you will have the following tests and procedures:

Bone marrow biopsy
A bone marrow biopsy and aspirate to test for hematological cancer is part of standard of care procedures for your cancer. During this procedure, an extra sample (3-5 ml) of bone marrow aspirate will be obtained after collecting all the samples needed to help with your cancer treatment. When you have blood drawn for lab tests from your port or arm, 2 additional small tubes of blood will be collected for research purposes.

If you have multiple myeloma, any leftover samples that are not used by the Pathology Department to complete the tests ordered by your doctor will be collected for the study so the sample is not wasted. These remaining samples will be outsourced to labs to run tests on equipment that is not available here at Wake Forest Baptist Health." This will include any unused samples from the bone marrow aspirate and/or blood samples. The lab is:

Proteona Pte Ltd
2 Jurong East Street 21 #04-20
Singapore 609601

Data and records of the work completed shall remain the property of Wake Forest University Health Sciences. Data and records of the work completed may be used by the Proteona Pte Ltd for its own internal research purposes in accordance with all applicable laws and regulations and in a manner that is consistent with authorizations granted by Institution's IRB. Institution retains the right to use all data generated under the Challenge for any purpose.

Storage of Biological Tissue

If you have leukemia or lymphoma and tissue or blood samples are left after performing the studies, we will store the remaining samples for possible future research. If you were to need another biopsy in the future, samples from then can be compared with stored samples to study how your cancer has changed. Any blood or tissue that is not used completely in this protocol will be stored in the laboratory at the Wake Forest Institute of Regenerative Medicine (WFIRM) which is part of Wake Forest Baptist Medical Center. You will be given a separate consent form to indicate whether you would like to donate tissue to the tumor bank.

How Long Will I Be in the Study?

You will be in the study as long as you are receiving care for your cancer. This will allow comparison with any future samples you may want to provide if you require more bone marrow biopsies as part of your treatment.

You can stop participating at any time. 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.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study may involve some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the procedures we are studying may include:

Risks of bone marrow aspirate

This bone marrow biopsy and aspirate is part of the standard of care procedures for treatment of your cancer. Researchers expect that the risks of sample collection will be comparable to the risks of the biopsy itself. Risks of a bone marrow biopsy include: infection, bleeding, pain at the biopsy site, injury to surrounding structures (muscles, nerves, bone), bruising.

Risks of blood draws

Drawing blood tests at the time of a bone marrow biopsy procedure is part of the standard of care for performing the tests. Researchers expect that the risks of sample collection will be comparable to the risks of having the routine blood drawn. Risks may include: infection or bleeding at the site, bruising.

Risks of Providing Confidential Information

Taking part in this research study may involve collecting information that you consider confidential or private. Efforts, such as assigning unique identifiers, coding research records, keeping research records secure, and allowing only authorized people to have access to research records, will be made to keep your information safe.

Reproductive Risks and other Issues to Participating in Research

This is not a treatment study and pregnancy testing is not required for the procedure since it is done with local anesthesia. Pregnant women and sexually active woman of childbearing potential who are capable of becoming pregnant have no increased risk of participating in this study but will require counseling by their oncologists if receiving chemotherapy from them.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from taking part in this research study. However, through your biological tissue sample, we hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

This is not a treatment study. Your alternative is to not participate in this study.

WHAT ARE THE COSTS?

All costs related directly to the study will be paid for by the study. However you or your insurance company will be charged, in the standard manner, for all procedures performed for your routine medical care and surgery. You will be responsible for costs of your routine care not covered by your insurer, including any applicable co-pays, coinsurances and deductibles.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published

in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

WILL YOU BE PAID FOR PARTICIPATING?

You will not be paid for participating in this study. Parking will be validated for study related visits. The findings from this research may result in the future development of products that are of commercial value. If the research investigators are able to develop new products from the use of your biological sample, there are currently no plans to share with you any future profits that may result if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest Baptist Comprehensive Cancer Center and the Myeloma Crowd Research Initiative. The sponsors are providing money or other support to Wake Forest University Health Sciences to help conduct this study. Wake Forest University Health Sciences, Timothy Pardee, MD, Ph.D. and Co-Investigatorshave an interest in the outcomes of this study, which could have financial value.

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, [redacted]

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

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 [redacted]

What About My Health Information?

In this research study any information we collect from you and/or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:**

- Demographic information
- Your response to treatment
- Laboratory results
- Tumor characteristics

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 diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer. Only the following people or organizations will be granted access to your Protected Health Information:

1) Dr. Pardee and other designated individuals at Wake Forest Baptist involved in collecting data relevant to the research project will have access to your medical record.

2) Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for an indeterminate period of time. This authorization does not expire. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Timothy Pardee, M.D., that you want to take away your permission to use and

share your Protected Health Information at any time by sending a letter to this address:

Timothy Pardee, MD, Ph.D.
Wake Forest Baptist Medical Center
Comprehensive Cancer Center
Medical Center Blvd.
Winston-Salem, NC 27157

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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.

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.

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, [redacted]

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 [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 (Printed):_____

Person Obtaining Consent:_____Date:_____Time:____ am pm

VOLUNTARY CONSENT

I give my permission to be recontacted in order to obtain additional blood samples in the future if there is a need, or desire, to study new therapies under this research project that could benefit other patients.

YES____ NO_____

I give my permission to be recontacted if results of the study are validated and a change in my treatment could possibly be of benefit to me.

YES___ NO ___