Title: Correlation of Serum Catecholamine With Emotional Stress in Men With Prostate Cancer: A Pilot Study

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Department/Section of *Hematology and Oncology*

Correlation of serum catecholamine with emotional stress in men with prostate cancer: A Pilot Study – CCCWFU 85316

Informed Consent Form to Participate in Research
Bart Frizzell, MD., 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 prostate cancer. 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 study is to determine if blood levels of epinephrine and cortisol, substances your body makes when you are stressed, rise or fall with how you are feeling and/or if those levels are related to clinical information related to your prostate cancer.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Approximately 61 people will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

In this research study, you will sign this informed consent and then have your medical history taken, you will be asked about medications you are taking and you will give a sample of blood (about 2-3 teaspoons). You will also answer questions from 2 short surveys so that your stress level can be determined. This is part of the research study and would not normally be done. You will give blood, answer the surveys, and provide medication information for every visit, for up to 5 visits.

The blood draws and medication review would occur with your normal visits to your doctor. However, part of this blood will be used for research to determine your epinephrine and cortisol levels. The stress surveys are a part of the research study.

If you take part in this study, you will have the following tests and procedures:

You will have approximately *2-3 teaspoons* of blood withdrawn from a vein *5 times*. The total amount of blood withdrawn during the study will be approximately *10-15 teaspoons.*
You will also fill out a survey to determine how stressed you are feeling at each visit to draw blood.

We can send copies of your test results to your personal physician. Even if you do not wish to have any of your medical information sent to your physician, you can still participate in this research study.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

STORAGE OF BIOLOGICAL TISSUE

Optional Prostate Tissue Donation in the Event of a Biopsy or Prostatectomy

If, during the study, it is recommended by your doctor to have a biopsy (a small piece of your prostate sampled) of your prostate or a prostatectomy (removal of your prostate) as a part of your normal care, you may also have a portion of this tissue used for future research. Your sample will be obtained at the Comprehensive Cancer Center at Wake Forest University Baptist Medical Center. The sample will be stored in the Tumor Tissue Core and it will be given only to researchers approved by Bart Frizzell, M.D.

If you have a prostate biopsy during this study would you be willing to have a portion of your tissue used for future studies?

_____Yes, a portion of the prostate biopsy can be used for future research.

_____No, a portion of the prostate biopsy cannot be used for future research.

All stored blood or tissue will be stored in the Tumor Tissue Core.

An Institutional Review Board (IRB) must also approve any future research study using your tissue sample.

Your prostate tissue sample will be stored de-identified, which means that no identifying information will be stored with it. Researchers will not know the name, date of birth, medical record number, social security number, etc., of the person who donated the sample.

The research that may be performed with your prostate tissue sample is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. It might help people who have diseases at some point in the future, but it is not known if this will happen. The results of the research performed with your prostate tissue will not be given to you or your doctor. The results will not be put in your medical record. The research using your prostate tissue sample will not affect your care.

Your prostate tissue sample will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of the research.

How Long Will I Be in the Study?

You will be in the study for a total 5 blood draws. This includes the blood draw at the beginning of the study and 4 more blood draws after that. The timing of the blood draws will be decided by your doctor but the total time will be about 1 year (12 months).

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 involves 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 blood draws and stress assessment surveys include:

Risks associated with the stress surveys:
As part of this study, you will be asked questions about how you are feeling emotionally. Filling out this form may increase those feelings you are being questioned about.

Risks associated with blood draws:
You may experience discomfort, bruising and/or bleeding where the needle is inserted. Occasionally, some people become dizzy lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia).

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as 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.

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. 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 study costs, including procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own

responsibility

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.

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 research study. Information about the research and any medications or devices you are being given as a participant 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.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment for taking part in this study. Parking will be validated for study related visits.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Wake Forest Baptist Comprehensive Cancer Center. The sponsor is providing money or other resources to help conduct this study.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and 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**:**
your health history, how you respond to study procedures, laboratory and other test results, and physical examinations.

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) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

2) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

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.

1) 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.

2) The study investigator and his/her staff, or others at Wake Forest University Health Sciences who oversee research

3) Other people or laboratories providing services for this research project on behalf of Wake Forest University Health Sciences and Wake Forest University Baptist Medical Center

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 at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-

identified. 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 Bart Frizzell, 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:

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.

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.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this 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. This could be for any reason the Principal Investigator feels necessary to adequately treat your disease.

Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

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, Bart Frizzell, M.D. at [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 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 (Printed):_____

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