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Consent to Participate in Research

Study Title: Pilot Trial to Evaluate Blood and Imaging Based Biomarkers for Aromatase Inhibitor Induced Musculoskeletal Syndrome

Principal Investigator: Pavani Chalasani, M.D., MPH

Sponsor: The University of Arizona Cancer Center

Summary of the research

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

You are being asked to participate in a study about how we might be able to predict who may be at greater risk for developing increased joint and muscle aches from the use of aromatase inhibitors. The study will take approximately 6 months and you will be asked to have blood drawn at 3 time points, and to complete study questionnaires at 3 time points. There is some risk of bruising and swelling from the blood draws. There is no direct benefit to you.

Why is this study being done?

Patients who take aromatase inhibitors for their breast cancer treatment are at risk of developing joint and muscle aches known as aromatase inhibitor induces musculoskeletal syndrome (AIMSS). Currently we do not know who is at risk of developing such side effects. This study is being done to evaluate blood studies as potential indicators of those who are at risk of developing AIMSS.

What will happen if I take part in this study?

Once your treating physician decides that you are ready to start on anastrozole as your routine standard of care cancer treatment, you will be asked to participate in the study. Your physician and/or the study team will explain the study and the study related procedures with you in detail. If you agree to those, you will sign this informed consent form and then the study screening procedures will start to determine if you can be enrolled in the study. Once it is

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determined you are eligible to enroll, you will be assigned a unique study ID number. You will then have a fasting blood draw for the study (30ml), and complete study related questionnaires.

At month 3 after starting anastrozole, you will be asked to have another fasting blood draw (30ml) and complete study questionnaires. At month 6 after starting anastrozole, the fasting blood draw (30 ml) and questionnaires will be repeated again. Your blood samples will be used as part of this study, and, with your permission, may also be stored for use in future studies.

All attempts will be made to include the study related fasting blood draws with your other routine lab work, and to administer the questionnaires during your regularly scheduled visits, however we cannot promise this can be done. In such case, you will be required to come to the clinic to complete any necessary study related procedures.

To summarize, if you take part in this study we will ask that you do the following:

- To learn about the study either from your oncologist or study team personnel. If you are interested, a member of the study team will ask you to sign a consent form
- Once the study doctor determines you are eligible, and BEFORE you begin your standard of care anastrozole treatment, you will be given 3 study related questionnaires to complete, you will have about 30 ml of blood drawn
- You will begin your standard of care anastrozole treatment under care of your oncologist
- At month 3 after starting anastrozole, you will be asked to complete the same 3 questionnaires you completed prior to your anastrozole treatment and you will have about 30 ml of blood drawn
- At month 6 after starting anastrozole, you will be asked to complete the same 3 questionnaires you completed previously, and you will have 30ml of blood drawn

How long will I be in this study?

You will be in the study until you complete all of the blood draws. You can decide not to continue with the study at any time point and can discuss this with your physician. Participating or declining to participate in this study will not affect you cancer treatment in any way.

How many people will take part in this study?

We anticipate enrolling up to 35 patients onto this study.

What risks, side effects or discomforts can I expect from being in the study?

<u>Blood Draw Risks</u>

This study involves blood draws. Risks of blood samples being taken include pain, bruising, bleeding, redness, swelling, infection and temporary redness of the skin at the place where the

needle is put into your arm. You may experience lightheadedness. Care will be taken to try to reduce these problems.

Risks Of Participating In Prospective Questionnaires

The primary risks of answering the questionnaires that are part of this study include breach of privacy and confidentiality, and emotional distress when answering questions about the types of symptoms you are experiencing, your quality of life, depression, anxiety, pain, or stigma. All efforts will be made to ensure the privacy health information is in compliance with HIPAA. You will not have to address any questions that you are not comfortable answering.

What benefits can I expect from being in this study?

There will not be direct benefits to you from this study. The long-term goal of this project is to develop unique blood biomarkers to identify patients at risk of developing AIMSS.

What happens if I am injured because I took part in this study?

If you are injured as a result of taking part in this study or for questions about a study-related injury, you may contact the Principal Investigator, Pavani Chalasani, MD. You can tell the doctor in person or call him/her at 520-626-0191.

If you suffer an injury from taking part in this study, you should seek treatment. You or your insurance company will be billed for those services. If you do not have insurance, you will be financially responsible for those expenses. This, however, does not waive your rights in the event of negligence.

The University of Arizona and Banner-University Medical Group have no funds set aside to pay for a research-related injury, added medical costs, loss of a job, or other costs to you or your family.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

Can I stop being in this study?

Your participation is voluntary. You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time, however any specimens or data that has already been collected prior to you leaving the study will be used. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The University of Arizona or Banner Health. If you are a student or employee at The University of Arizona, your decision will not affect your grades or employment status.

What other choices do I have if I do not take part in this study?

You may choose not to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

When may participation in the study be stopped?

You can decide to leave the study at any time by notifying your study doctor.

The study doctor may withdraw you from the study for one or more of the following reasons:

- The study doctor decides that discontinuing is in your best interest and continuing participation could be harmful to you
- You need treatment or receives treatment not allowed in the study
- Unanticipated circumstances
- The study is cancelled upon investigators assessment that risks outweigh benefits or new information is known to the investigators on the protocol

What are the costs of taking part in this study?

We will not be treating your cancer as part of this study. You and/or your health plan/ insurance company will need to pay for all of the costs of treating your cancer.
There is no cost to you for the study related blood draws other than your time.

Will I be paid for taking part in this study?

There is no compensation for you for taking part in this study.

Will my study-related information be shared, disclosed, and kept confidential?

The University of Arizona has rules to protect information about you. Federal and state laws also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The people working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may collect other information including your name, address, date of birth, phone number, social security number and other details. Photocopies of actual treatment records may be required as part of this review. By signing the consent form, you allow access to your medical records, without removal of identifying information such as your name, initials, date of birth, sex, race, and location of the research study.

Generally, only people on the research team will know that you are in the research study and will see your information. However, there are some exceptions, and the Principal Investigator may give information about you to people outside of the University of Arizona if required.

It is anticipated that there will be circumstances where your study related information and PHI will be released to persons and organizations described in this form. If you sign this form, you give permission to the research team to use and/or disclose your protected health information (PHI) for this study. Your information may be shared or disclosed with others to conduct the study, for regulatory purposes, and to help ensure that the study has been done correctly. These other groups include:

- Representatives of the U.S. Food and Drug Administration (FDA),
- Office for Human Research Protections or other federal, state, or international regulatory agencies
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- Your health insurance company
- *Banner University Medical Group and Banner Health*
- The University of Arizona (UA), The University of Arizona Cancer Center (UACC) and the UA Institutional Review Board
- Your primary care physician or a specialist taking care of your health.

Your PHI may no longer be protected under the HIPAA privacy rule once it is disclosed by the research team.

What study-related information and PHI will be obtained, used or disclosed from my medical record at Banner?

Information related to this research study that identifies you and your PHI will be collected from your past, present, and future hospital and/or other health care provider medical records.

The PHI you are authorizing to be used and/or disclosed in connection with this research study is:

- We will collect information regarding your name, date of birth, medical history, treatments you are receiving currently

Demographic information to be disclosed may include, but is not limited to, your name, address, phone number, or social security number.

Your existing health records may include information related to the diagnosis or treatment of sexually transmitted disease (STD), acquired immunodeficiency syndrome (AIDS), human immunodeficiency virus (HIV), other communicable diseases, genetic information (e.g., genetic testing), and/or alcohol and/or drug abuse. The study staff and study sponsor's monitor may see this information while reviewing your regular health records for this study, but they WILL NOT create, collect, or disclose this type of information for the purposes of this research study.

If information from this study is presented publicly or published in a medical journal, you will not be identified by name. Your blood samples and extracted medical records information will be labeled with a coded identification number only.

When will my authorization expire?

There is no expiration date or event for your authorization. Therefore, unless you cancel this authorization (as instructed below) this authorization will continue to be effective.

Do I have to sign this authorization form?

You do not have to sign this authorization. However, if you decide not to sign, you will not be able to participate in this research study; and it will not affect any non-study Banner Health medical treatment or health care, payment, enrollment in any health plans, or benefits.

What do I need to know if I decide to cancel my authorization?

After signing the authorization, you may decide to cancel your previous authorization for the research team to use your PHI. If you cancel the authorization, you will no longer be able to stay in the research study. Please note that any PHI collected before you cancel the authorization may still be used. You may revoke the authorization by contacting the Principal Investigator in writing. Contact information is under "Who can answer my questions about the study" at the end of this document.

Will access be limited to your research study record during this study?

You may not have access to the research information developed as part of this study until it is completed. If you have any questions you can reach out to your treating physician or Principal Investigator Pavani Chalasani MD,MPH at 520-626-0191.

Will my data or specimens be stored for future research?

As previously explained, we will be collecting three blood samples as part of this study. The collection of these blood samples is not optional, and these samples will be used to evaluate for certain inflammation markers which might predict development of AIMSS. If there are any blood samples remaining at the end of the study, we would like to store them for use in future projects. The study unique ID number will be assigned to the stored blood samples. If you are willing to allow us to store your remaining blood samples for future use, you must specify your consent below. Consent for the future use of the remaining blood samples is entirely voluntary and may be withdrawn at any time.

If you decide now that any remaining blood samples can be kept for research, you can change your mind at any time. Contact your study doctor and let him or her know that you do not want us to use your blood, and it will be destroyed and will no longer be used for research. If your blood has already been used for research it will not be possible to get it back.

Please initial next to one option below for the future use of any remaining blood samples. You do not have to agree to the future use of remaining blood samples to take part in the rest of the study.

I agree that any remaining blood samples can be saved and used for future research projects (please initial):

Yes _____

No _____

Optional Research Activity
Optional research activity is part of this project. If you choose to participate in this optional activity your PHI shall be included for this optional activity.

By initialing the line below, you agree to allow your PHI to be used and/or disclosed for the optional Study activity referenced above.
_____ Initials

Future Use of PHI
Future research activity is part of this project. If you choose to participate in the future research activity your PHI will be included in this future research activity.

By initialing the line below you agree to allow your information to be used and/or disclosed for the optional future research referenced above.

_____ Initials

Will my specimens be sold for commercial profits?
The information/specimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or other compensation from products developed using the information/specimens.

Will I hear back on any results that directly impact me?
You will not receive any clinically relevant results discovered about you and/or the general subject population.

Will Whole Genome Sequencing be done with my specimen?
No, whole genome sequencing is not a part of this study.

Who can answer my questions about this study?
You can get further information about the research or voice concerns or complaints about the research by calling the Principal Investigator, Pavani Chalasani MD, MPH at 520-626-0191. If you have any type of after-hours emergency or need to speak to someone after hours, please call the Banner-University Medical Center Tucson Paging Operator at 520-694-6000 and ask for the hematologist/oncologist on call.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact

the Human Subjects Protection Program at 520-626-6721 or online at http://rgw.arizona.edu/compliance/human-subjects-protection-program.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact the Principal Investigator Pavani Chalasani MD, MPH at 520-626-0191.

If you have any questions or concerns about the authorization for access to your PHI, you should contact Sue Colvin, Banner Research Regulatory Affairs Director, at (602) 839-4583 or sue.colvin@bannerhealth.com. You may also request and will be provided a copy of the Notice of Privacy Practices.

To cancel your authorization for access to PHI you must notify the *Principal Investigator/Research Team* in writing at the following address:

Principal Investigator, Pavani Chalasani, MD, MPH
University of Arizona Cancer Center
1515 N. Campbell Avenue
Tucson, Arizona 85724
United States
Fax: 520-626-2225

An Institutional Review Board responsible for human subjects research at The University of Arizona reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Signing the consent form

I have read (or someone has read to me) this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study and I authorize the use and/or disclosure of my PHI. I am not giving up any legal rights by signing this form. I will be given a signed copy of this form**.**

Printed name of subject	Signature of subject	Date

Investigator/Research Staff

I have explained the research to the participant or the participant's representative before requesting the signature(s) above. There are no blanks in this document. A signed copy of this form has been given to the participant or to the participant's representative.

Printed name of person obtaining consent	Signature of person obtaining consent	Date