CONSENT FORM AND INFORMATION ABOUT

Prevention of Heart Failure Induced by Doxorubicin with Early Administration of Dexrazoxane (PHOENIX 1)

to be conducted at
THE UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

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Participant Name **Medical Record Number**

Key Information for Prevention of Heart Failure Induced by Doxorubicin with Early Administration of Dexrazoxane (PHOENIX 1)

This first part gives you key information to help you decide if you want to join the study. We will explain things in more detail later in this form.

We are asking if you want to volunteer for a research study about the use of dexrazoxane in cancer patients. By doing this study, we hope to find a lower effective dose of dexrazoxane to prevent heart failure induced by doxorubicin.

Please ask the research team if you have any questions about anything in this form. If you have questions later, contact the researcher in charge of the study. The contact information is at the top of this page.

What will happen if I join the study?

If you are eligible for this research study, your part in this research may last up to one week and include five visits.

During the study, you will receive a single IV infusion of dexrazoxane and have blood drawn at multiple time points. We will explain this process later in this form.

The purpose of the study is to learn whether a dose lower than the FDA approved dose would be effective.

Do I have to join this study?

No. It is okay to say no. You will not lose any services, benefits, or rights you would normally have if you decide not to join. If you decide to take part in the study, it should be because you really want to volunteer.

What do I need to know to decide if I should join this study?

People decide to join studies for many reasons. Here are some of the main things you should think about before choosing to join this study.

Main reasons to join the study

- ✓ There is no direct benefit to you but the knowledge gained may help in the future treatment of people with cancer.

Main reasons <u>not</u> to join the study

- ✓ You may experience discomfort or pain during the IV infusion or blood draw.
- ✓ There is a potential for loss of confidentiality. Someone may find out you were in this study and learn something about you that you did not want them to know.

These are just some of the reasons to help you decide if you want to join the study. We will explain more about the risks, benefits, and other options to joining the study later in this form.

Tell the study team if you decide that you do not want to be in the study. Remember, it is okay to say no. You can still get your medical care from UAMS if you are not in the study.

University of Arkansas for Medical Sciences Informed Consent Form

- **We are asking you to be in a research study. You do not have to join the study.**
- **You can still get your medical care from UAMS even if you are not in the study.**
- **Take as much time as you need to read this form and decide what is right for you.**

Why am I being asked to be in this research study?

- We want to learn more about the use of dexrazoxane in cancer patients.
- By doing this study, we hope to find the dose of dexrazoxane that will be effective to prevent heart failure induced by doxorubicin.
- We are asking people like you, who are healthy female volunteers to help us.
- We will consent up to 50 people, adults, 18-65 years of age, in order to enroll 25 to the study.

What if I don't understand something?

- This form may have words you do not understand. If you would like, research staff will read it with you.
- You are free to ask questions at any time – before, during, or after you are in the study.
- Please ask as many questions as you would like before you decide if you want to be in this study. If you decide to take part in the study, it should be because you really want to volunteer.

What will happen if I say yes, I want to be in this study?

You may be screened for COVID each time you come to the Winthrop P Rockefeller Cancer Institute, depending on the UAMS standards.

There will be five visits in this study. We will draw blood at each visit.

Visit 3, 4, and 5 are visits to have one blood drawn of 2 teaspoons.

Visit 1

During the first visit, we will see if you qualify to be in the study. We will:

- Ask you some questions about your heath and medicines you may be taking.
- Obtain a blood sample to check your liver and kidney functions and make sure you are not pregnant or have anemia. A urine pregnancy test can be used in place of the blood sample to test if you are pregnant.
- Check your vital signs. We will record your height, weight, heartbeat, respirations, blood pressure, and temperature. We will ask you to rate your pain on a scale from 1-10.

If you qualify, we will do these things:

This study has five groups. Each group will receive a designated dose of dexrazoxane. You will be assigned to the current study group.

A time will be scheduled for you to return to the study site to begin your participation.

Visit 2

For your second visit, you will go to the Winthrop P Rockefeller Cancer Institute. Prior to your 12-hour infusion, you will need to take a urine pregnancy test. You will receive an intravenous (IV) catheter (a small plastic tube inserted through a needle into a vein on your arm). About 4 teaspoons of blood will be drawn from this IV line for baseline blood tests. You will receive dexrazoxane through IV infusion for 15 minutes (+/- 5 minutes).

Two teaspoons of blood will be drawn hourly from the IV catheter for the next 12 hours. Meals vouchers will be provided to you during this 12 hour infusion visit at Visit 2.

We will check your vital signs before and after the infusion, six hours after the infusion, and 12 hours after infusion when you are discharged. We will record your heartbeat, respirations, blood pressure, and temperature. We will ask you to rate your pain on a scale from 1-10.

On visits 2, 3 and 4, we will be testing your blood for two enzymes. These enzymes indicate how well dexrazoxane is working in your body.

Visit 3

You will go to the Winthrop P Rockefeller Cancer Institute. You will have blood drawn 24 hours after dexrazoxane infusion.

Visit 4

You will go to the Winthrop P Rockefeller Cancer Institute. You will have blood drawn 48 hours after dexrazoxane infusion.

Visit 5

You will go to the Winthrop P Rockefeller Cancer Institute. To make sure you do not have a very rare side effect, you will have blood drawn for routine blood count one week after the infusion. If your blood test shows a need for follow up, you will have an additional test one week later. The cost of the additional visit will be paid by the study, however, no additional payment will be provided.

We will take a total of about 34-38 teaspoons of blood for the whole study. You will be monitored for any symptoms you may experience.

You will need to refrain from drinking alcohol until you have completed your 48th hour blood draw after infusion.

The IV infusion and all blood samples are required to participate in this study. The collections of blood are for research only.

You will be given a parking voucher for each visit.

How long will I be in this study?

You will be in the study for about 1 week. There will be five visits, including one visit that will last for about 12 hours. During this extended visit, you will have blood drawn (through your IV) once an hour for 12 hours. During this visit, meals will be provided to you.

You will return to have your blood drawn 24 hours after your infusion and then again at 48 hours after your infusion.

Finally, one week after your infusion, you will return to the study site for a blood draw.

You will be given a parking voucher for each visit.

What if I say no, I do not want to be in this study?

- Nothing bad will happen because of what you decide.
- You can still get medical care at UAMS.

What happens if I say yes but change my mind later?

- You can stop being in the study at any time.
- Nothing bad will happen because you change your mind and leave the study.
- You can still get medical care at UAMS.
- If you decide to stop being in the study, inform a member of the study team.

Will it cost me anything to be in the study?

The study will not cost you anything. You and/or your health insurance will be required to pay for those services, supplies, procedures and care that you continue to require for your routine medical care during this study (meaning the procedures and services you would have had even if you were not in the study). You will be responsible for any co-payments and/or deductibles as required by your insurance for such routine medical care.

Will I be paid for being in the study?

Yes. You may be paid a total of $400. This is to reimburse you for your time and inconvenience. You will be issued a Greenphire, Inc. ClinCard, which is a debit card that your stipends are loaded onto and can be used at your discretion. When a visit is completed, funds will be approved and loaded onto your card. Once approved to be released to your card, the funds will be available for use.

If you change your mind and decide not to complete the study, you will only be paid for the parts you complete. You will be paid $50 for the screening portion of this study. You will be paid $80 for receiving the infusion. You will be paid $120 ($10 per blood draw) to complete the first 12 hours of blood draws. You will receive an additional $50 for each return visit to the study site for blood draws (at 24 hours, 48 hours and one week after the infusion). If your lab values require you to return for the additional, conditional visit two weeks after the infusion, the cost of your visit will be paid by the study, however, you will not receive any additional compensation. A parking voucher will be provided for each visit. Meals will also be provided to you during the 12 hour infusion visit at Visit 2.

In accordance with the United States IRS guidelines, payments paid to an individual that are equal to or greater than $600.00 per calendar year (January-December) are reportable to the IRS. If your payments are equal to or greater than $600.00 in a calendar year, you will receive a 1099-MISC form to file with your taxes. The 1099-MISC will be sent in January of the following year as required by the IRS. If your payments were not greater than $600 in the calendar year, you will not receive a 1099-MISC form. No taxes will be withheld from payments made to you. You are responsible for reporting payments to you on your state and federal tax returns, as applicable, and paying any taxes that may be due.

If you are a recipient of Social Security Income (SSI), Social Security Disability Income (SSDI) recipient, or other income based assistance programs, the additional income from this study will increase your yearly income and possibly make you ineligible for these benefits. Please ask your study coordinator for details. Please contact your Social Security Office or your financial advisor if you have any questions

Will being in this study help me in any way?

We do not think that being in this study will help you personally. However, it may help people with being treated for cancer in the future.

What are the risks of being in this study?

There is a risk that someone could find out that you were in the study and learn something about you that you do not want others to know. We will do our best to protect your privacy, as explained in more detail later in this form.

Blood testing risks: Taking blood from you may cause some discomfort from the needle stick, bruising, or very rarely, infection.

Possible risks, discomforts, and/or side effects of dexrazoxane include:

- Pain on injection: This is the most likely side effect.
  To reduce the likelihood of this side effect, we will administer dexrazoxane through infusion, not injection. If needed, we will check your catheter and slow down the infusion rate to minimize this side effect.
- The superficial skin and deeper tissue under the skin might suffer damage (tissue death):
  Notify study staff if you experience this side effect. (very low likelihood, not serious)
- Myelosuppresion (reduced blood counts)
  We will ask you to have blood drawn for blood counts one week after you received dexrazoxane infusion. (low likelihood, serious) In the very rare situation that you

have reduced blood counts, we will help you get further observation and medical care at UAMS or your local provider. This treatment will be billed to you or your insurance company.

- Severe allergic reaction, such as anaphylaxis. Anaphylaxis is a serious, potentially life-threatening, whole-body allergic reaction.: (very low likelihood, serious)
  If you develop an allergic reaction to dexrazoxane, the infusion will be stopped.

Other common possible side effects that may need medical attention:

- Bluish color
- changes in skin color
- chest pain
- chills
- cold hands and feet
- cough
- difficult or labored breathing
- fever
- hoarseness
- lower back or side pain
- pain, redness, or swelling in the arm or leg
- painful or difficult urination
- pale skin
- sneezing
- sore throat
- swelling of the hands, ankles, feet, or lower legs
- tenderness
- tightness in the chest
- troubled breathing
- unusual bleeding or bruising
- unusual tiredness or weakness

Due to the risk of myelosuppression (reduced blood counts), you should not take aspirin, NSAIDs, and over-the counter supplements for at least 1-2 weeks after infusion of dexrazoxane.

Report fever, any bleeding from gums or nose, blood in stool or urine. If you experience any of these, you may need an earlier visit to evaluate for myelosuppression.

What if I get sick or hurt while I am in this study?

If you get hurt or sick when you are here for the study, we will help you get the care you need. This may include first aid, emergency care, and any follow-up care you need.

- If you are not here and get hurt or sick, and you think it is because of the study, do these things:
  - ✓ call your doctor – or if an emergency, call 911
  - ✓ give your doctor or ER staff
    - the name of this study – Prevention of Heart Failure Induced by Doxorubicin with Early Administration of Dexrazoxane (PHOENIX 1)
    - the name of the head researcher for this study – Hui-Ming Chang, MD
    - a copy of this form if you have it
  - ✓ after business hours, call (501) 686-7575, or (501) 526-0847
- This treatment will be billed to you or your insurance company. No other form of payment is available.

Reminder: You do not give up any of your legal rights by agreeing to be in this study or by signing this form.

What are the alternatives to being in this study?

You may choose to not participate in this study.

Can I be taken out of the study even if I want to continue?

Yes, the study doctor can take you out of the study if:

- You do not follow study instructions.
- It is not in your best interest to continue.
- The study is stopped for any reason.

What information will be collected about me in the study?

During the study, we will need to learn private things about you, including:

- General contact and background information about you, such as age, race, and other demographic information.

- Results of physical exams, lab tests, and your response to study treatment and side effects, as well as your history of previous illnesses and conditions that you have now.

Who will see this information? How will you keep it private?

- The study team will know your name and have access to your information.
- We will do our best to make sure no one outside the study knows you are part of the study.
- We will take your name off the study information that we collect from you during the study.
- We will give your information a code, so that no one can identify you.
- If we share the results of the study in medical journals or other publications, we will not include your name or anything else that could identify you.
- There are people who make sure the study is run the right way. These people may see information that identifies you. They are
  - ✓ OHRP (Office for Human Research Protections), a federal agency
  - ✓ UAMS Institutional Review Board
  - ✓ Other institutional oversight offices
- State law requires that we tell the authorities if we learn about possible abuse or that you might hurt yourself or someone else.

Where will my information be kept? For how long will it be kept?

- Once we give your information a code, we will keep the key to this code in a locked file.
- Only the study staff will be able to link it to you.
- The information may be kept indefinitely on a password-protected file.
- Your samples will be destroyed after the study is complete.
- We will put information about you from the study in your medical record.
- We will put a copy of this form in your medical record.

If I stop being in the study, what will happen to my information collected in the study?

- If you wish to have your information taken out of the study, call Dr. Hui-Ming Chang at 501-686-8274.

Will my information or samples from the study be used for anything else, including future research?

No. Your information or samples will be used only for this study. It will not be used for future research, either with or without identifiers.

Will you tell me the results of the study?

No. However, we plan to publish the results in an academic journal. (What we publish will not include anything that can identify you though.)

Will you tell me anything you learn that may affect my health?

Yes. If we learn something about you that might be important for your health, we will tell you.

What if new information comes up about the study?

We will tell you if we learn anything that may change your mind about being in the study.

Where can I find more information about this clinical trial?
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website any time.

What if I have questions?

- Please call the head researcher of the study – Hui-Ming Chang at 501-686-8274– if you
  - ✓ have any questions about this study
  - ✓ feel you have been injured in any way by being in this study
- You can also call the office at UAMS that supervises research if you cannot reach the study team, have questions about your rights as a research participant, or want

to speak to someone not directly involved with this study. To do so, call the UAMS Institutional Review Board at 501-686-5667 during normal work hours.

By signing the document, I am saying:

- ✓ I agree to be in the study.
- ✓ I know that joining this study is voluntary.
- ✓ Someone has talked with me about the information in this form and answered all of my questions.

I know that:

- ✓ I can stop being in any and all parts of the study at any time and nothing bad will happen to me.
- ✓ I can still get medical care at UAMS no matter what I decide.
- ✓ I can call the office that supervises research (UAMS Institutional Review Board) at 501-686-5667 if I have any questions about the study or about my rights.
- ✓ I do not give up any of my legal rights by signing this form.

I agree to be part of this study:

_____ _____

Your name (please print) Your signature

_____

Date

_____ _____

Printed name of person obtaining consent Signature of person obtaining consent

_____

Date