Official Title: LCI-HEM-BMT-IMPPACT-001: A Prospective Interventional Trial Of Pharmacogenomic-Guided Supportive Care In Hematopoietic Cell Transplantation
NCT04727827
IRB-Approved Date: 2/8/2022

ATRIUM HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY
AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**Levine Cancer Institute/ "A Prospective Interventional Trial Of Pharmacogenomic-Guided Supportive Care In Hematopoietic Cell Transplantation"**
Protocol Number:	**LCI-HEM-BMT-IMPPACT-001**
Principal Investigator: (Study Investigator)	**Justin Arnall, PharmD**
Telephone:	**[redacted] (24 Hours)** **[redacted] (24 Hours)**
Address:	**Atrium Health** **Levine Cancer Institute-Carolinas Medical Center** **[redacted]**

Please read this form carefully. Take time to ask the study investigator or study staff as many questions about the study as you would like. The study investigator or study staff can explain words or information that you do not understand. Reading this form and talking to the study investigator or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign and date your name at the end of this form. You cannot take part in this research study until you sign and date this form.

INTRODUCTION

The study investigator and study staff are asking you to participate in a research study at Levine Cancer Institute (LCI) and Atrium Health (AH) that will be testing the use of a pharmacogenomic (PGx) panel (a form of genetic test) to help manage medicine prescribed to you during and after hematopoietic stem cell transplantation. These medications (also referred to as "supportive care medications") may include drugs to help with pain, depression, nausea and other transplant related symptoms. You are being asked to participate in this research study because you are going to have a hematopoietic stem cell transplant.

PGx looks at how an individual's DNA affects his or her response to drugs. DNA is found inside cells in your body and contains your genes. These genes tell your body how grow, develop and function. Genes are passed down from parents to their children. The PGx panel looks at differences

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in DNA and how that person might respond to a certain drug. By knowing this information, the investigator can select a drug and/or dose better suited for that individual.

The information gained from PGx testing being applied to prescribing supportive care medication is investigational and **not** approved by the Food and Drug Administration (FDA) at this time.

There is no investigational treatment as part of this study. Supportive care medications prescribed during transplant are considered standard of care. The procedures done for research are cheek swab collection and questionnaires.

Taking part in this study is entirely voluntary. There is no out of pocket cost for PGx testing. You will be one of approximately 130 subjects taking part in this study at Levine Cancer Institute. Your participation will last approximately 5 months. Your participation may be terminated by the study investigator.

STUDY ASSESSMENTS AND PROCEDURES

Registration:
You will be asked to fully read this form, then sign and date the consent. Once consented, we will make sure you meet all conditions to participate in the study. Next, either you or a staff member will collect two samples from the inside of your cheek using a swab. Cheek swab collection is non-invasive and should not cause you any discomfort. The purpose of this sample is to look at your DNA by PGx testing in hopes of better selecting supportive care medications and/or medication doses you may receive during your hematopoietic (the formation of all types of blood cells) stem cell transplant. A hematopoietic stem cell transplant is also called a bone marrow transplant. A bone marrow transplant is a procedure that infuses healthy blood-forming stem cells into your body to replace your damaged or diseased bone marrow. You will receive a transplant as a part of your standard care. The results from the cheek swab usually take 5-7 days. Your cheek swab will not be used for any other type of testing and will be stored in the Molecular Biology Laboratory at LCI. Once testing is complete, your sample will be discarded per laboratory procedures. Your samples will be labeled with identification such as your name and date of birth, so we are able to place the results in your medical record. Your cheek swab results will be available to for you to review at any time. If you decide to not participate in the study before PGx testing results have been confirmed, your sample will be discarded.

Baseline: (Prior to transplant)
Prior to your hematopoietic stem cell transplant, demographic information will be collected (date of birth, gender, ethnicity) as well as height/weight, medical/treatment history, medications you are currently taking and drug allergies. During the study, you will be asked to not take any illicit drugs or substances. You will also be asked to complete an ESAS questionnaire to check symptoms you may be having such as pain, nausea, unhappiness, and nervousness. Questionnaires will preferably be completed electronically (using REDCap) but may also be completed by paper, or over the phone. REDCap is a web platform that manages surveys and it has been validated to protect your privacy and personal health information. The ESAS questionnaire should take about 5 minutes to complete.

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Study Visits: (Days 30, 60 and 100)
During each study visit, you will be asked to complete an ESAS questionnaire. These may be done electronically, by paper or over the phone. Specialty Pharmacy staff will review your medications and any side effects that you may be having. Your provider will make necessary dose or medication changes.

YOUR ROLE IN THE STUDY

Taking part in a research study can be an inconvenience to your daily life. Please consider the study time commitments and responsibilities as a research subject when you are deciding to take part. Your responsibilities as a study subject include the following:

- Tell the truth about your medical history and current conditions.
- Tell the study investigator if you have been in a research study in the last 30 days or are in another research study now.
- Tell the study investigator about any problems you have during the study.

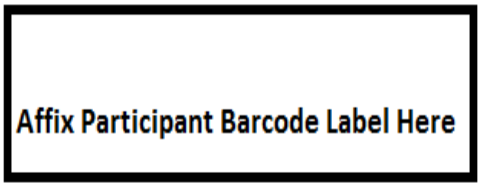
POTENTIAL RISKS OF THE STUDY

Emotional Distress:
Some of the questions in the ESAS survey could cause emotional distress. If this occurs or you have any questions or concerns while completing the survey, please stop and share this information with a research designee. Knowledge of PGx test results may result in emotional distress. You will be counseled on your test results by a trained pharmacist.

Electronic Confidentiality:
REDCap technology and protocols have been validated to protect your privacy and personal health information for survey collection process. Your questionnaires will contain only a subject identification number, and your first and last initial. However, because personal information is being transmitted over the internet, there is still some risk of accidental disclosure of your personally identifiable medical information. All of the records will be stored in a way that only allows the appropriate study staff access to this data with a very strong password. You will be notified immediately if there is any reason to believe that your privacy has been violated.

Specimen Confidentiality:
There is a potential risk that your confidential health information may be released during the processing of your specimen for research. Everything possible will be done to ensure your privacy and confidentiality is maintained. Only your study investigator and a small number of study staff will know your identity.

Genetic Testing Privacy Risks:
Results of your pharmacogenomic panel will be provided to you, at your request. It is up to you whether or not you would like to share this information with your other healthcare providers.
A federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans and most employers to discriminate against you based on your genetic information.



This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that the sponsor will get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that the sponsor will get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans and all employers with 15 or more people must follow this law.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance or long-term care insurance.

Unknown Risks:
You might have side effects or discomforts that are not listed in this form. Some side effects may not be known yet. New ones could happen to you. Tell the study investigator or study staff right away if you have any problems.

ALTERNATIVES TO BEING IN THE STUDY
You may choose to not take part in this research study. Your study investigator can discuss the alternatives and the risks and benefits of these alternatives with you.

NEW FINDINGS
Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

POTENTIAL BENEFITS OF BEING IN THE STUDY
You may or may not receive any benefit from being in the study. It is possible that using the pharmacogenomic results to prescribe supportive care medications may help your symptoms. The information gained as a result of this study may help us know whether genetic information is useful for prescribing medications and could help other patients in the future.

COSTS OF BEING IN THE STUDY
You will not have any out of pocket costs for PGx testing. Your clinic visits as well as prescriptions are considered standard of care and will be billed to your insurance.

YOUR PAYMENT FOR BEING IN THE STUDY
You will not be paid for taking part in this study.

None of the investigators asking you to participate in this study has received or will receive money or other benefits for personal use from the study sponsor. However, the sponsor will give money or other benefits to a research fund, foundation, educational institution, or other organization with which the investigator or study staff is associated.

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COMPENSATION FOR INJURY

In the event that you are injured as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner. You will be responsible for deductibles, co-payments, and co-insurance. There are no plans to pay or give you other compensation for the injury.

If you become ill or are hurt while you are in the study, get the medical care that you need right away.

For insurance or other payment reporting purposes, we may need to know some information about you like your name, date of birth, and Medicare Beneficiary Identifier (MBI). This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare.

In no way does signing this consent form waive your legal rights nor does it relieve the investigators, Sponsor or involved institutions from their legal and professional responsibilities.

CONFIDENTIALITY

The records of this study will be kept private. If any report about this research is published, we will not include any information that will make it possible to identify you. However, there is some risk that de-identified data might be re-identified. Also, your record for this study may be reviewed and/or photocopied by the Sponsor, by Atrium Health, or by representatives of the Food and Drug Administration or other government agencies.

To ensure that your information collected for this study will be kept private, your name will not be used whenever possible. A code will be used instead of your name. All of your study data will be kept in a secure location.

During this study, we will collect some of your private information to include medical and treatment history. All subject specific identifiers will be removed. Your cheek swab specimen will contain information specific to you such as your name or date of birth and will not be confidential. This specimen and the information gained will not be used for future research studies or distributed to another investigator for future research without additional informed consent from you. Your samples will not be used for profit.

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AUTHORIZATION TO USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION

If you wish to participate in this research study, you _____

Printed Name of Research Subject

must sign this Authorization. By signing this Authorization, you give all healthcare providers, including Atrium Health, permission to use or disclose (release) your protected health information, both past and present, for the research study described here:

A Perspective Interventional Trial of Pharmacogenomic-Guided Supportive Care in Hematopoietic Cell Transplantation

The protected health information that we may use or disclose (release) for this research may include all information in your medical record, such as results of physical examinations, medical history, lab tests, or certain health information indicating or relating to a particular condition.

The health information listed above may be used by and/or disclosed (released) to:

- Study investigator and research staff
- Regulatory or other governmental authorities of the United States or other countries based on this study
- Other persons or agents authorized by the study sponsor
- Atrium Health employees
- Other persons or agencies as required by law or allowed by federal regulations
- Advarra Institutional Review Board (Advarra IRB) or Data Safety and Monitoring Boards.

Atrium Health is required by law to protect your protected health information. By signing this Authorization, you authorize Atrium Health to use and/or disclose (release) your protected health information for this research study. Those persons who receive your protected health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your protected health information with others without your permission, if permitted by laws governing them. Your protected health information may then no longer be protected by the Privacy Rule.

Please note that you do not have to sign this Authorization, but if you do not, you may not receive research-related treatment through this study. However, Atrium Health may not condition (withhold or refuse) your other Atrium Health providers treating you on whether you sign this Authorization. You may change your mind and withdraw (take back) this Authorization at any time, except to the extent that Atrium Health or the Sponsor has already used or disclosed your protected health information based on this Authorization. To withdraw this Authorization, you must write to the Study Investigator at the address listed on the first page of this form.

No publication or public presentation about the research described above will reveal your identity without another Authorization from you. If all protected health information that does or can identify you is removed, the remaining information will no longer be subject to this Authorization or federal rules (such as the Privacy Rule) and may be used or disclosed for other purposes.

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When the research for which the use or disclosure is made involves treatment and is conducted by Atrium Health: To maintain the integrity of this research study, you generally will not have access to your personal health information related to this research until the study is complete.

At the conclusion of the research study and at your request, you generally will have access to your protected health information. Access to your protected health information in a medical record is described in the Notice of Privacy Practices provided to you by Atrium Health.

When conducting research, the data and results may be used or disclosed for further treatment outcomes research or to research a secondary result. This Authorization will remain in effect after the end of the current study, and any future related secondary study unless it is revoked by the you in writing as described above.

_____

Signature of Research Subject

_____

Printed name of Research Subject

_____

Date

EMAIL COMMUNICATION

By providing my email address and phone number, I give permission for Atrium Health and its representative (including third-party agents if applicable) to send me information, reminders, and messages using either of these means of communication. I authorize Atrium Health to send me unencrypted messages using this means of communication, and I understand and accept the risks associated with doing so. Email is not to be used for emergency situations.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, and/or concerns or complaints regarding this research study, contact**:**

- By mail:
  Study Subject Adviser
  [redacted]

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- [redacted]
- or call **toll free**: [redacted]
- or by **email**: [redacted]

Please reference the following number when contacting the Study Subject Adviser: Pro00048025.

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.

BEING A STUDY VOLUNTEER AND WITHDRAWING FROM THE STUDY
Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, that will not in any way harm your relations with your investigators or with Atrium Health. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your investigators or Atrium Health.

STATEMENT OF CONSENT
I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.

_____ ____/____/____ _____
Signature of Research Subject Date Time

_____
Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING CONSENT
I have carefully explained to the subject the nature and purpose of the above study. There has been an opportunity for the subject to ask questions about this research study. I have been available to answer any questions that the subject has about this study.

_____ ____/____/____ _____
Signature of Person Explaining Consent Date Time

_____
Printed Name of Person Explaining Consent

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