Official Title: LCI-SUPP-NOS-PGX-001: Evaluating the Use of Preemptive Pharmacogenomic Testing to Personalize Supportive Oncology
NCT04500301
IRB-Approved Date: 6/16/2022

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

Sponsor / Study Title:	**Levine Cancer Institute / "Evaluating the Use of Preemptive Pharmacogenomic Testing to Personalize Supportive Oncology"**
Protocol Number:	**LCI-SUPP-NOS-PGX-001**
Principal Investigator:	**Jai Patel, 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. Before any study-related tests and activities are performed, you will be asked to read, sign, and date this consent form. You will discuss the Informed Consent Form with the study staff and the study investigator in person, during a telephone call or via a secure video conference call.

If you agree to take part in the study, you will sign and date the informed consent form either by signing and dating a copy of the printed paper form or by signing and dating electronically using the REDCap platform (secure web application for building and managing online surveys and databases) on a mobile device or a desktop computer.

After you have signed and dated this paper or electronic Informed Consent Form, you will be given a paper copy or be able to save a PDF copy for your records and/or email a copy to yourself. 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.

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INTRODUCTION

The study investigator and his associates (the study staff) are asking you to participate in a research study at Levine Cancer Institute (LCI) and Atrium Health (AH). You will be one of approximately 80 subjects testing the use of a pharmacogenomic (PGx) panel (a form of genetic test) to help manage drugs prescribed to you for pain and/or depression.

Cells in your body contain DNA. DNA is the substance that makes up all genes. Genes are passed on from your parents and help guide the growth, development, and function of your body. For example, some genes control the color of your hair or eyes. There are many natural differences or variations in DNA from one person to another. These variations may affect the way a person responds to a particular drug. Pharmacogenomics (PGx) is the study of how one's DNA influences his or her response to drugs. A PGx panel tests for these variations in DNA.

Understanding if a person has these differences may help a doctor to select the most suitable drug for that person. The purpose of this study is to better understand how genetic test results from a PGx panel can be used to guide drug prescribing for your pain and/or depression.

The possible benefit of using this test to guide your pain and depression therapy will be assessed by recording your PGx results, medications prescribed, and pain and depression scores while on study. The results of this test may also help to guide the management of other medications related to these genes.

You are being asked to take part in this study because you reported having pain and/or depression during your visit to the Department of Supportive Oncology's palliative medicine clinic. You will be treated by providers in the Department of Supportive Oncology at the Levine Cancer Institute.

This application of the PGx panel is investigational and **not** Food and Drug Administration (FDA) approved.

There is no investigational treatment as part of this study. All supportive care treatments, including those for pain and depression, are considered standard of care. The procedures done for research purposes will involve cheek swab collection to test for the PGx panel and PHQ9 (questionnaires to measure your depression) and a questionnaire at the end of the study about pharmacogenetic testing.

Participation in this study is completely voluntary and there will be no cost for PGx testing for you. Choosing not to participate in the study or leaving the study after you join will not result in any penalty or loss of benefits to which you are otherwise entitled. However, please note that the FDA requires that any information collected up to the point of your withdrawal cannot be removed from the study.

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HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

You may be one of approximately 80 subjects participating in this study at Levine Cancer Institute Morehead. Your participation may last up to approximately 28 weeks. Your participation may be terminated by the sponsor or the study investigator without your consent.

STUDY ASSESSMENTS AND PROCEDURES

Registration (one visit):

First, you will be asked to fully read, sign and date this consent form (in-person or electronically using REDCap). If you are willing to take part in the study, we will check whether you have all conditions to include you in the study and collect the information about your pain and depression level (ESAS score) reported during your first visit to the Department of Supportive Oncology's palliative medicine clinic (or your first visit after visiting the palliative medicine clinic more than a year prior).
Second, after making sure you can be included in the study, 2 cheek swabs will be collected either in-person at Levine Cancer Institute or by yourself at your home. If you choose to collect the sample at home, a shipment with study supplies will be sent to you by Levine Cancer Institute (who will be provided with your address). You will be provided with 2 swabs for the inside of your cheek and the instruction on how to collect the sample and ship overnight only on Monday through Thursday. You will be asked to complete a form with some information about yourself and mail the cheek swabs and form back to Levine Cancer Institute within 48-72 hours.

Cheek swab collection is non-invasive. The purpose of it is to collect a sample of your DNA for PGx testing. The results of this test will be available in approximately 5 days after receiving it by laboratory.

Samples will be used for PGx testing only. Specimens will be stored in the Molecular Biology Laboratory for approximately one week after sample receiving. Once your PGx results have been confirmed, then all samples will be discarded according to laboratory procedures.

Samples will be labeled with your name, so we can relate each set of results back to you. Results of the test will be uploaded to your medical chart.

If you decide to quit the study before PGx testing results have been confirmed, your samples will be discarded.

Baseline (one visit):

This visit will happen in the Levine Cancer Institute Department of Supportive Oncology's palliative medicine clinic (in person or virtually) or over the phone with research staff.

Demographic information will be collected (race, ethnicity, insurance status, and zip code).

You will be asked questions about your medical history, your current disease, questions about your well-being and activities of daily life and any treatments you have received.

Any medications you are currently taking, and drug allergies will be checked as well.

You will be asked to complete PHQ9 (questionnaire to measure your depression) electronically or by phone within 2 business days prior to your study visit or in paper during study visit. Your provider will be notified of responses.

You will be asked to complete ESAS (questionnaire to measure your pain level as a part of standard of care).

Study Visits (4 study visits, including the final visit):
You will be asked by a provider, registered nurse, pharmacist, or a member of the research team to complete PHQ9 (questionnaire to measure your depression) electronically or by phone within 2 business days prior to your study visit or in paper during study visit. Your provider will be notified of responses.

You will have (3) study visits approximately every 4 weeks (in person or virtually). Study assessments also can be completed over the phone.

Any changes in medications you are currently taking, and drug allergies will be checked at these visits as well.
You will be asked to complete ESAS (questionnaire to measure your pain level as a part of standard of care).
Also, we will track whether PGx test results impacted a medication or dose change.
We will count your inpatient and outpatient visits at medical facilities.

The final visit will happen approximately 4 weeks after the third study visit. We will ask you to complete an electronic questionnaire sent using your email about pharmacogenetic testing within 30 days after the final visit. You also will have an option to complete this questionnaire by phone call or during your clinic visit on paper. The results may be useful in identifying how subjects felt about being part of the study and receiving PGx testing. We will also ask demographic questions concerning annual household income and education level.

Throughout your participation in the study, your medications will be managed by your providers, using PGx results if needed, and collected as part of the study. You may always contact the clinic if you feel like you need your medications adjusted in between clinic visits.

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ADDITIONAL/MORE DETAILED INFORMATION

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.

RISKS OF THE STUDY

The potential risks are limited to loss of confidentiality, cheek swab collection, emotional distress and knowledge of PGx test results (see below Privacy risks of genetic testing). If your genetic research data are shared with unauthorized users, you may be at risk of loss of the privacy of your health data. This risk is minimized by protections described in the Confidentiality section below.

Risk of the emotional distress:
Some questions in the questionnaires could create emotional distress. If you have a distress or confusion the questionnaire process will be interrupted. Some people feel uncomfortable when answering questions about the quality of their life. Though it is always better to have fully completed questionnaires, you do not need to answer any questions that make you feel uncomfortable.

Knowledge of PGx test results may result in emotional distress. You will be counseled on your test results by a trained pharmacist.

Privacy risks of electronic consent:
REDCap technology and protocols have been validated to protect your privacy and personal health information for electronic consent process. 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 to access 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.

You may be emailed a PDF copy of this signed and dated consent form. There may be risks of loss of privacy and confidentiality if the PDF copy of this consent form is viewed and/or stored on a personal electronic device (PED), especially if that PED is shared with other users or is lost, hacked, or subject to a search warrant or subpoena. Also, the PDF copy of the consent may not be able to be permanently removed from a PED.

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Privacy risks of genetic testing

Results of your PGx panel will be uploaded into your medical record, and provided to you, at your request. It is up to you whether or not you would like to share this further information.
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.

BENEFITS OF STUDY TREATMENT

You may or may not benefit from participating in this study. There is a possibility that the use of genetics to guide your pain and depression management may help improve your symptoms. The results of this study may help us determine whether or not genetic information is useful to manage drugs for pain and depression, which may help other people in the future.

ALTERNATIVE TO BEING IN THE STUDY

You may choose not to participate in this study and instead receive routine care as recommended by your clinician. Your clinician can discuss the alternatives and the risks and benefits of these alternatives with you. Please ask any questions you may have and take as much time as you need to make your decision.

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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.

COSTS AND COMPENSATION FOR PARTICIPATION IN THIS STUDY

There will be no out of pocket costs to you for the PGx testing. Your clinic visits and prescriptions will be billed to your insurance in the usual manner.

For more information on clinical trials and insurance coverage, you can visit the National Cancer Institute's web site at http://cancer.gov/clinicaltrials/understanding/insurance-coverage. You can print a copy of the "Clinical Trials and Insurance Coverage" information from this web site. Another way to get the information is to call 1-800-4-CANCER (1-800-422-6237) and ask them to send you a free copy.

You will not receive payment for taking part in this study.

STUDY STAFF PAYMENT/FINANCIAL DISCLOSURE

None of the doctors 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 doctor or study staff is associated.

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. You do not waive any legal rights by signing this consent form.

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 we may have to check to see if you receive Medicare and if you do, report the payment we make 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.

Affix Participant Barcode Label Here

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.

This study involves the collection of your private information and biospecimens. 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 studies without additional informed consent from the subject.

Your biospecimens will not be used for profit.

EMAIL COMMUNICATION. By providing my email address, I give permission for Atrium Health and its representative (including third-party agents if applicable) to send me information, reminders, and messages using this 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.

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:

LCI-SUPP-NOS-PGx-001: Evaluating the Use of Preemptive Pharmacogenomic Testing to Personalize Supportive Oncology

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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
- Study sponsor and/or its associated companies
- 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.

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.

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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 you in writing as described above.

_____

Signature of Research Subject

_____

Printed name of Research Subject

Date

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

Please reference the following number when contacting the Study Subject Adviser: Pro00045081.

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 doctors 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 doctors or Atrium Health.

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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

Affix Participant Barcode Label Here