Official Title: LCI-GI-NOS-NAV-001: A Randomized, Controlled Prospective Trial Evaluating The Impact Of A Nurse Navigation Program on Patients with Gastrointestinal Cancers Undergoing Oncological Treatment
NCT04602611
IRB-Approved Date: 5/8/2023

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

Sponsor / Study Title:	**Levine Cancer Institute / "A Randomized, Controlled ProspeCtive Trial Evaluating The Impact Of A NurSe Navigation Program on Patients with GastrointeStinal Cancers Undergoing Oncological Treatment"**
Protocol Number:	**LCI-GI-NOS-NAV-001**
Principal Investigator: (Study Doctor)	**Mohamed Salem, MD**
Telephone:	[redacted] **(24 Hours)** **(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 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. 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 Florence eConsent platform. Written consent can be done in person or remotely using electronic consent.

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 copy for your records and/or email a copy to yourself.

Affix Participant Barcode Label Here

INTRODUCTION

The Study Doctor listed on the first page of this form is asking you to participate in this research study of an Oncology Nurse Navigation program (ONN) provided by LCI Patient Navigation Program (LPNP) at Levine`s Cancer Institute (LCI) and Atrium Health (AH). You are being asked to take part because you have a GI cancer and are planning to start or just have started your anticancer therapy. The purpose of this study is to learn about the impact of ONN on the frequency of your visits to Emergency Department or Urgent care and inpatient hospital admissions. Also, we would like to know about your cancer care with or without ONN in certain timepoints.

You will be one of approximately 347 subjects who will be randomly (like flipping a coin) selected to receive or not receive ONN service. You will have an equal chance of being assigned to either study group. The only study procedure that will be different from your standard treatment is a satisfaction survey during your treatment. It will be collected during your routine visits, by phone call or utilizing virtual care. Some questions in the survey may distress you, also always there is a risk to privacy. If you are willing not to complete the survey you still can participate in the study.

Participation in this study might or might not benefit you. Not everyone who participates in a research study will benefit personally. Sometimes, your participation in the research study will be of benefit to society by helping researchers to learn more about the impact of ONN on the number of healthcare visits. Participation is completely voluntary. 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. The study investigator or the sponsor can end your participation in the study without your consent. There is an alternative to your treatment, to proceed without ONN at all. Navigation services will be provided at no cost. Your clinic visits and prescriptions will be billed to your insurance in the usual manner.

You will participate in the study for up to approximately 8 years.

STUDY ASSESSMENTS AND PROCEDURES

Screening procedures

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 to the study.

Second, after making sure you can be included in the study, your medical history, demographics (DOB, sex, race, marital status, income, insurance status, education level, zip code) will be collected.

During the Intervention

Your satisfaction survey will be collected at 4 weeks and 10-14 weeks from the study beginning. You will be provided with the option to answer the survey questions electronically or during a clinic visit. Every 3 months we will collect some information about your healthcare visits and missed visits.

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Survival Follow-up
If you stop receiving cancer treatment, relocate to an institution other than LCI, relocate to an LCI institution that does not offer navigation services, or decide you do not want to continue to receive navigation services (only applicable to patients who were randomized to receive navigation) you will not be asked to participate in any study procedures except to receive phone calls from research staff approximately every 6 months to check how you are doing.. These phone calls will continue for up to approximately 8 years after you are enrolled to the study.

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 doctor if you have been in a research study in the last 30 days or are in another research study now.
- Tell the study doctor about any problems you have during the study.
- Tell the study doctor about any healthcare visits during the study.

RISKS OF THE STUDY

The potential risks are limited to loss of confidentiality, and emotional distress. The confidentiality 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. You don't have to answer any question that makes you uncomfortable.

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 will 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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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 doctor or study staff right away if you have any problems.

COSTS OF BEING IN THE STUDY

There is no cost for your participation in this study.

YOUR PAYMENT FOR BEING IN THE STUDY

You will not be paid for being 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.

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.

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.

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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.

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:

A Randomized, Controlled ProspeCtive Trial Evaluating The Impact Of A NurSe Navigation Program on Patients with GastrointeStinal Cancers Undergoing Oncological Treatment (ACCESS)

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

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- 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 Doctor 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.

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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AGREEMENT FOR COMMUNICATION BY EMAIL AND PHONE

All study subjects are legally required to receive a signed and dated copy of any consent form which they complete. The following two fields, Email and Phone Number, are not required, but are needed in order to send you an emailed PDF copy of your completed, signed and dated consent form if you completed it electronically. If these fields are not completed, we will need to mail you a paper copy of your completed, signed and dated consent form. Your email may be used to send you a questionnaire about pharmacogenomic testing. We are legally obligated to remind you that while email is convenient, it is not legally considered a secure form of 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.

Email: _____

Phone Number: _____

_____

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

Please reference the following number when contacting the Study Subject Adviser: Pro00046658.

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

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