Official Title: *LCI-HN-MUC-LOX-001*: Phase II Randomized Trial of an Oral Formulation Containing a Mucoadhesive Polymer Hydrogel Vehicle (MucoLox®) to Mitigate Mucositis Symptoms in Head/Neck Cancer Patients Receiving Radiation ± Chemotherapy
NCT#03461354
IRB-Approved Date: *09/29/2020*

ATRIUM HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Sponsor / Study Title:	**Levine Cancer Institute/ Phase II Randomized Trial of an Oral Formulation Containing a Mucoadhesive Polymer Hydrogel Vehicle (Mucolox®) To Mitigate Mucositis Symptoms in Head/Neck Cancer Patients Receiving Radiation +/- Chemotherapy**
Protocol Number:	**LCI-HN-MUC-LOX-001**
Principal Investigator:	**Jai N. Patel, PharmD, BCOP**
Telephone:	[redacted]
Address:	**Levine Cancer Institute** [redacted]

INTRODUCTION

The study doctor and his associates (the investigators) are asking you to participate in a research study at Levine Cancer Institute (LCI) and Atrium Health testing a Mucolox®-based oral formulation to prevent oral mucositis (irritation or sores in the mouth) in patients who are receiving radiation with or without chemotherapy to treat head/neck cancer. The purpose of this study is to determine if using mouth rinses with Mucolox® will prevent severe mucositis. You are being asked to take part in this study because you have head/neck cancer for which you will receive radiation with or without chemotherapy.

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You have the option not to participate. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation. 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.

This study is being carried out under the sponsorship of Levine Cancer Institute (LCI) and Professional Compounding Centers of America, who will be supplying the Mucolox® and sodium bicarbonate mouth rinses used in this study.

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WHY IS THIS STUDY BEING DONE?

Mucositis is a common complication of many cancer treatments, but is especially common with treatment for head and neck cancer. Radiation can damage the lining of the mouth and the glands that make saliva, which can upset the healthy balance of normal bacteria in your mouth. Radiation and chemotherapy slow or stop the growth of fast growing cells, such as cancer cells. Normal cells in the lining of the mouth are also fast growing, so radiation and chemotherapy can also slow or stop new cell growth to heal the lining of the mouth. Mucositis is very painful and can make it difficult to eat or drink. Sometimes cancer treatment needs to be decreased or stopped because of these oral complications. If we can prevent or lessen these complications, your quality of life may improve and treatment may work better because it does not have to be interrupted or decreased.

The current standard of care treatment to prevent mucositis is mouth care with sodium bicarbonate rinses. However, about half of patients still experience severe mucositis. This study is being done to see if rinsing with Mucolox® will better protect the tissues inside the mouth and prevent severe mucositis during treatment with radiation with or without chemotherapy.

HOW MANY SUBJECTS WILL TAKE PART IN THE STUDY?

You will be one of up to 60 subjects participating in this study at Levine Cancer Institute. Thirty subjects will receive sodium bicarbonate mouthwash and thirty will receive the Mucolox® rinse.

HOW THE STUDY WORKS

Before you begin the study (Baseline):

To participate in this study, you will need to review, sign and date this consent form and provide authorization for the release of your medical records for research purposes. By doing so, you are giving us permission to determine if you are eligible to participate in this study. To be eligible, you must:

- Have confirmed head/neck cancer scheduled to receive at least a 28-day course of radiation to the head/neck area
- Be at least 18 years of age
- Not currently have more than mild mucositis
- Not have any mouth or throat condition that would make you unable to use the mouth rinse
- Able and willing to complete the Oral Mucositis Daily Questionnaire
- Able and willing to swish and spit the oral formulation

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During the study:

People taking part in this study will receive 1 of 2 different mouth rinses: sodium bicarbonate mouthwash, which is the current standard mouth care to prevent mucositis for patients receiving radiation and chemotherapy, or Mucolox® rinse. This is so that we can compare the results of the investigational treatment with what is currently being used as standard treatment. The study treatment plan that you receive is decided by a process called randomization. Randomization means that the study treatment is assigned based on chance. It is a lot like flipping a coin, except that it is done by computer. You and your study doctor will not pick which study treatment you get, and you will not be told which mouth rinse you are receiving. Your study doctor will know which mouth rinse you receive in order to make treatment decisions if you develop mucositis. You will swish and spit the mouth rinse at home three times a day for 28 days. You should not eat or drink for 1 hour after using the rinse.

The day that you start the mouth rinse is Day 1 of the study, which should be the day you start radiation or the day after. During the time that you are receiving treatment with the mouth rinse, you will have an assessment done weekly (+/- 2 days) on Days 8, 15, 22, and 29 (last assessment). If you are scheduled to be seen in the clinic as part of your standard care, study assessments, such as documentation of any medications that you are taking and any side effects you are experiencing will be performed during the clinic visit. If you are not being seen in the clinic during these time-points, the study assessments will be done over the phone with research staff. If at any time your mouth symptoms become severe your study doctor will make changes to your mouth care. If you were receiving Mucolox® rinse, you will stop being in the study and your doctor will decide how to best treat your symptoms. If you were receiving sodium bicarbonate rinses, you will be given the option to use the Mucolox® rinse for 7 days or until the end of your 28 days of treatment, whichever is longer, to see if it will help treat your mucositis.

After the Final Assessment on Day 29 is completed (either in the clinic or over the phone), your participation in the study is complete. You may stay on the study longer if all of the study questionnaires (see next section) have not been completed or returned by the Final Assessment time-point. Research staff may attempt to collect the questionnaires after this time-point (by collecting the questionnaires from you at a later time-point or over the phone). After the questionnaires have been collected, then your participation in the study will be complete.

Questionnaires

You will be provided a short questionnaire to fill out before starting radiation and every day while you are using the mouth rinse which should be completed after you take your last dose of mouth rinse. If you have an email address and access to an electronic device, such as a computer, cell phone, or tablet, you will be asked to complete the questionnaires electronically using an electronic device. You may receive periodic email reminders to complete your daily questionnaire. If you are unable or prefer not to complete the questionnaires electronically, paper questionnaires will be

provided to you in the clinic to be completed at home. The paper questionnaires will need to be brought back to the clinic and returned to clinic or research staff at each visit that you have while you are receiving the mouth rinse. If you choose to complete the questionnaires by paper and you are not able to return all of the questionnaires, the questions in the questionnaire may be reviewed with you over the phone with research staff.

RISKS

You may have side effects while you are on this study. Everyone taking part in the study will be carefully watched for side effects. However, side effects may occur that are not yet known. Side effects seen on research studies can result from a subject's disease, the drug under study, other drugs the subject is taking, other diseases the subject has, or a combination of these.

Side effects can be mild or very serious. Your healthcare team may give you medicines to lessen side effects. Many side effects go away after you stop taking the study drug. In some cases, side effects can be serious in that they can be long lasting, may never go away, may result in hospitalization, or may result in death.

We expect side effects from the mouth rinses to be minimal. Possible side effects for either treatment on this study are related to mouthwashes in general, and may include:

- Mouth discomfort
- Allergic reactions
- Worsening of mucositis symptoms
- Mouth ulcers
- Dry mouth
- Unpleasant taste

You should talk to your study doctor about any side effects that you have while taking part in the study.

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

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WILL I BENEFIT FROM PARTICIPATING IN THIS STUDY?

We hope that this study treatment will help you personally, but it might be that you do not gain any benefit from the study treatment. Information from this study may help you and/or other people with your disease in the future.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

You may choose not to participate in this study and receive standard treatment as recommended by your study doctor, such as other mouth care regimens to prevent mucositis. Please talk to your study doctor about the treatment options and their risks and benefits. Please ask any questions you may have and take as much time as you need to make your decision.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

You or your insurance company will be charged for continuing medical care and/or hospitalization in the usual manner. You or your insurance company will not be charged for tasks that are being performed by the Research Team for research purposes only. Professional Compounding Centers of America will supply the Mucolox® and/or Sodium Bicarbonate mouthwash at no charge while you take part in this study. You will not receive payment for taking part in this study.

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 may wish to discuss coverage with your insurance company before agreeing to participate in this research study.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will not be paid for being in this study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

If you become ill or are hurt while you are in the study, get the medical care that you need right away. Emergency medical treatment will be billed to you and/or your insurance company. No funds have been set aside to compensate you in the event of injury. However, you are not giving up any legal rights to seek compensation for injury by signing this form.

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WHAT IF I WANT TO QUIT THE STUDY LATER?

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, your decision not to participate will not in any way harm your relationship with your doctors or with Atrium Health. There is no penalty or loss of benefits. You are free to stop being in the study if you change your mind after entering it. This would not harm your relationship with your doctors or Atrium Health.

- You may always say no. You do not have to take part in the study.
- If you start a study, you may stop at any time. You do not need to give a reason.
- If you do not want to be in a study or you stop the study at a later time, you will not be penalized or lose any benefits.
- If you stop, you should tell the study staff and follow the instructions they may give you.

Information already contributed to the study will remain in the study even if you choose to withdraw. If you choose to withdraw from the study, please notify the study doctor in writing at the address on page 1 of this consent form.

The study doctor may choose to withdraw you from the study for any reason even if you do not want to stop.

We will tell you about new information or changes in the study that may affect your health, welfare, or willingness to stay in this study.

If you stop taking part in this study, any questionnaires which you have already completed will remain de-identified and part of the study.

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied by Atrium Health, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- Atrium Health
- Representatives of governmental regulatory agencies, such as the Food and Drug Administration (FDA), that are involved in keeping research safe for people

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- The institutional review board responsible for oversight of the study at this site

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

A description of this clinical trial will be available on *https://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.

AUTHORIZATION TO USE AND DISCLOSE YOUR PROTECTED HEALTH INFORMATION

If you wish to take part in this clinical study, you will be asked to sign this consent form. It allows the study sponsor (LCI) and investigator (Dr. Patel) to collect and process any relevant personal health information collected from you during the study. These are activities routinely carried out during all clinical studies.

You have been told that personal information about you (including sensitive personal health information, such as your medical history and your racial/ethnic origin if relevant to the study) will be reviewed, collected on a computer database, stored in electronic or manual files, audited, and/or otherwise processed by:

- the clinical study sponsor-investigator, Dr. Patel, and research staff,
- regulatory or other governmental authorities of the United States and other countries,
- other persons authorized by the study sponsor-investigator,
- Atrium Health employees,
- other persons or agencies as required by law or allowed by federal regulations.

You have been told that your personal data are being collected and processed to:

- check your suitability to take part in the study,
- monitor activity with the treatment under study,
- compare results with those of other subjects in the study,
- support the development of other study protocols.

You have been told that your personal information may be processed within the U.S. or elsewhere in the world or transferred to or from the U.S. for review, processing and/or storage by an associated company or a carefully selected third-party organization. By signing this document, you explicitly consent to the transfer of your personal information, including sensitive personal information, collected during this clinical study, for review, processing, and/or storage. Your personal health

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information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, the groups are committed to keeping your personal health information confidential.

You may refuse this authorization to transfer your personal information. If you choose not to agree to this authorization, you will be ineligible to participate in the study. If you decide not to sign this authorization, that will not harm your relations with your doctors or with Atrium Health

You have the right to inspect your medical record at any time. Your research record may be unavailable until the conclusion of the study. At that point, it will be available. Please speak with the study doctor if you desire to access your record.

You have been told whenever your personal information is processed, it will be kept confidential and secure, to the best of our ability. It will be used only for the purpose for which it was collected.

This Authorization does not have an expiration date. You have been told that according to the guidelines for good clinical practice, the study sponsor-investigator will keep your personal information for at least 6 years. If you do not withdraw this Authorization in writing, it will remain until the study is terminated. If you wish to revoke authorization to use your personal information, you will notify the study doctor in writing at the address on page 1 of this consent form.

Some of the data obtained from your record prior to your revocation may still be used if considered necessary for the study.

AGREEMENT FOR COMMUNICATION BY EMAIL

If you agree to complete the questionnaires electronically, the following field, Email, is not required, but is needed in order to send you the questionnaire and periodic reminders to complete the questionnaires. 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, 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.

Email:_____

_____ ____/____/____ _____

Signature of Research Subject **Date** **Time**

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FINANCIAL DISCLOSURE

None of the doctors asking you to participate in this study have received or will receive money or other benefits for personal use from the company that developed the drug used in this study. The institution will receive some funding from Professional Compounding Centers of America to do the research.

GETTING ANSWERS TO YOUR QUESTIONS OR CONCERNS ABOUT THE STUDY

You can ask questions about this consent form or the study (before you decide to start the study, at any time during the study, or after completion of the study). Questions may include:

- Who to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a study subject;
- Eligibility to participate in the research;
- The study doctor's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;
- Other questions, concerns, or complaints.

Contact the study doctor or study staff at Atrium Health, listed on the first page of this form, with any questions, concerns or complaints.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT YOUR RIGHTS AS A RESEARCH SUBJECT

This study has been reviewed by an Institutional Review Board (IRB). This Committee reviewed this study to help ensure that your rights and welfare are protected and that this study is carried out in an ethical manner.

For questions about your rights as a research subject, contact:

- By mail:
  Study Subject Adviser
  Advarra IRB
  [redacted]
- or call **toll free**: [redacted]
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the study subject adviser: Pro00024266.

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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 my questions were answered to my satisfaction. I am not giving up any of my legal rights by signing this form. I will receive a signed and dated copy of this form for my records.

_____ ____/____/____ _____
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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