A Clinician-Focused Nudging Intervention to Optimize Post-Surgical Prescribing

Principal Investigator:

Daniel B. Larach, M.D., M.S.T.R., M.A.

Assistant Professor of Anesthesiology, Vanderbilt University Medical Center

Sponsor:

The National Institute on Aging

P30 Grant #5P30AG024968

NCT05299528

Larach Informed Consent

Record ID

_____

You may save or print a blank copy of this consent form for your records if you wish. After you submit this form, you will be offered the opportunity to save or print a signed copy of this consent form.

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VUMC Institutional Review Board
Informed Consent Document for Research
Principal Investigator: Daniel Larach, MD

Study Title: A Post-Surgical Follow-up of Patient Pain Management

Institution/Hospital: Vanderbilt University Medical Center

Revision Date: March 23, 2022
Date of IRB Approval: [INSERT APPROVAL DATE EXACTLY MATCHING IRB STAMP after obtaining approval]
Date of IRB Expiration: [INSERT EXPIRATION DATE EXACTLY MATCHING IRB STAMP after obtaining approval, if applicable]

Name of Participant:

_____
(First Last)

Age:

_____

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information: The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

Physician prescribing is deeply connected with opioid use disorder: Most Americans misusing prescription opioids were either directly prescribed these medications or received them from a friend or relative with a prescription, and most current heroin users started opioid use with prescribed medication. Surgical prescribing comprises an increasing proportion of first-start opioid prescriptions to opioid-naïve patients; 6% of these patients develop new persistent opioid use postoperatively. Up to 70% of prescribed postoperative opioids go unconsumed and become a reservoir for potential diversion or misuse.

The study team is recruiting surgeons who would like to receive information about their patients' opioid consumption during the post-operative recovery period. There is a risk of breach of confidentialty; however, no information gathered will be entered into your patients' medical record or entered into your employment records. This is for research only and your participation is voluntary. Data from this study will be stored in a REDCap and available only to the study team.

Detailed Information: The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you are a general, gynecologic, orthopedic, or neurological surgeon at VUMC. The study team would like to reach out to select post-surgery patients to survey their pain management experience. Study results will provide information about surgical patients' opioid use.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study.

Procedures to be followed and approximate duration of the study:

After you sign this consent, the study team will run queries in medical records to compile a list of surgical patients to be contacted. The study team will then reach out to your patients and gather prescription and quality of recovery information. This process will take around 3 months.

Expected costs:

There is no cost to you to take part in this study.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

Breach of confidentiality: No information from this study will be entered into patient medical records or employment records. Data will be stored in REDCap which is only available to the study team using VUMC ID and password. User rights for REDCap are maintained by the PI of the study.

Compensation in case of study-related injury:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study.
The results of this study may help providers know more about prescribing and managing post-operative pain.

b) The benefits you might get from being in this study.
While you won't benefit directly from this study, you may learn more about pain management using opioids.

Study Results:

You will not be told about the results of this study.

Compensation for participation:

You will not be paid to take part in this study.

Circumstances under which the Principal Investigator may withdraw you from study participation:

If you are taken out of the study, you will be told the reason.

What happens if you choose to withdraw from study participation?

Please notify Daniel Larach, MD at daniel.larach@vumc.org if you want to withdraw from the study.

Contact Information.

If you should have any questions about this research study or possibly injury, please feel free to contact Daniel Larach, MD at daniel.larach@vumc.org.

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to contact the Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Study records will be stored in REDCap and permission will managed by the PI. Study team members must use their own VUMC ID/password to log-in. This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

Research data will be stored in REDCAP. In order to maintain your privacy the study team will not share the results of this study in a way that can identify you.

STATEMENT BY PERSON AGREEING TO PARTICIPATE IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to participate.

◯ Yes ◯ No

Signature of patient/volunteer:

(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign.)

Date:

(Date of Volunteer Signature)

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Informed Consent Document for Research

Study Title:	A Clinician-Focused Nudging Intervention to Optimize Post-Surgical Prescribing
Version Date:	June 28, 2022
PI:	Daniel Larach, MD, MSTR, MA

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
You are being asked to take part in this research study because you received a prescription for pain medicine after your recent surgery at Vanderbilt University Medical Center (VUMC).

The purpose of this research study is to learn more about how prescription pain medicines are used by patients during recovery after surgery and if providing this information to surgeons would change the amount of pain medicine they prescribe.

A member of the study team will contact you and ask you about your pain control after surgery and complete a quick pill count. Answering the questions will take about 10 minutes of your time. The study team will also review your medical records to look at the amount of pain medicine you were prescribed and whether you had any issues with pain after going home following surgery.

The results of this research study will not help you; but it will help doctors learn more about how these pain medicines are used by patients during recovery from surgery.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you received a prescription for pain medicine following your surgical procedure at VUMC. A member of the study team will contact you and ask you about your pain control after surgery and complete a quick pill count. Answering the questions

will take about 10 minutes of your time. This information is for research only and will not be recorded in your medical record.

The study team will also review your medical records to look at the amount of pain medicine you were prescribed and whether you had any issues with pain after going home following surgery.

Other patients of your surgeon are going to be asked to participate in the study as well. Afterwards, we will combine everyone's answers in a way that patients will not be identified and then provide feedback to your surgeon about how many pain pills his or her patients use after surgery. We are interested in seeing if this feedback affects the way doctors prescribe pain medicine in the future.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether you still want to be in this study.

Side effects and risks that you can expect if you take part in this study:
Discomfort: Answering questions about your pain may make you uncomfortable; if this happens, please let us know. The answers you provide will not be entered into your medical record or shared in a way that can identify you.

Breach of Confidentiality: There is a slight risk of breach of confidentiality; however, study data will be entered into a secure research database that is only available to people who work on the study. No information that identifies you will be released to your doctors or put in your medical records.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study: The results of this research study will not help you; but it will help doctors learn more about prescribing pain medicine after surgery.

Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

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There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Daniel Larach at **615-875-1852.** If you cannot reach the research staff, please page the study doctor at **615-835-0867.**

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
You may be taken out of the study if the doctor feels it is not good for you to continue or if you withdraw consent. If you are taken out of the study, you will be told the reason.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor.

Clinical Trials Registry:
A description of this clinical trial will be available on 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 Web site at any time.

Confidentiality:
All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. Study records will be kept in a research database with very limited access. The study doctor will control access to the database and members of the study team will use their private log-in to access the database. To protect your privacy, we will not release your name.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
You will not be contacted to be told the results of this study.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with othe rs. If

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your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____