The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: Restrictive Opioid Prescribing after Surgery for Prolapse and Incontinence: A Randomized Controlled Trial
Sponsor: N/A
Principal Investigator: Cecile Ferrando, M.D. M.P.H., Phone: (216) 444-0642
After hours phone contact #: (216) 444-2200. Ask the operator to page the 'GYN on call.'

You are being invited to participate in a research study. A research study is designed to answer specific questions about new ways to prevent, detect, and treat disease. Being in a research study is different from being a patient. The purpose of this document is to provide a written summary of the discussion and exchange of research information you had with the research team. It is also for use as a reference during the study.

KEY INFORMATION

The following is a short summary of this research study to help you decide whether or not to be a part of this research study. More detailed information is included later on in this document.

What should I know about a research study?

- Someone will explain this research study to you.
- You can choose whether or not to take part.
- You can agree to take part and then later change your mind.
- Your decision whether or not to participate will not be held against you.
- You can ask all the questions you want before you decide.

What is the purpose, procedures and duration of this study?

We invite you to take part in a research study because you are scheduled to undergo surgery.

The first study is being done to learn if a new postoperative pain relief schedule is sufficient compared to standard practice, and to determine usage patterns of pain medication after surgery.

You will be asked to complete 3 brief questionnaires before your surgery. After your surgery, you will be asked to log your pain levels and pain medication use daily for 7 days. At your follow-up visit, you will be asked two questions about your satisfaction level with your pain relief regimen and your expectations about postoperative pain. Your participation in the research study will last about 6 weeks and will conclude at your postoperative follow-up visit.

More detailed information can be found under the section labeled: "Information on the Research."

Why might you choose not to participate in this research study?

The main risks associated with this study are those related to the potential pain and discomfort you may experience during postoperative recovery. Your doctor and surgical team will try to

ensure that your pain is adequately controlled. Another risk of participating in this study is related to your privacy; however, many measures are taken to ensure that your privacy is maintained.

More detailed information about the risks of this study can be found in the section labeled "Risks."

Why might you choose to volunteer for this study?

You may not receive direct benefit from being in this study. However, taking part in this study may help us to better understand how we can help manage postoperative pain in patients undergoing surgery in the future.

More detailed information about the benefits of this study can be found in the section labeled "Benefits."

What are my other choices if I do not take part in this study?

Taking part in this study is voluntary. The alternative is not to participate. More detailed information about the alternatives to this study can be found in the section labeled "Alternatives."

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

The purpose of this study is to learn if a new postoperative pain relief schedule is sufficient compared to standard practice, and to determine usage patterns of pain medication after surgery. Postoperative pain is usually managed with multiple pain-reducing medications, which include opioids, nonsteroidal anti-inflammatory drugs (NSAIDs) like ibuprofen (Advil, Motrin), other non-opioid pain relievers like acetaminophen (Tylenol), and anticonvulsants used to treat nerve pain, such as gabapentin (Neurontin). Opioids are powerful pain medications that can be prescribed in pill form after surgery. Examples of opioids include oxycodone (Roxicodone) and hydromorphone (Dilaudid). In standard practice, patients are usually sent home after surgery with a combination of pain medications that includes a prescription for opioids. Not all patients after urogynecologic surgery will need opioids to control their pain. The ultimate goal of this study is to help determine factors predicting the need for opioids after gynecologic surgery.

How Many People Will Take Part in this Study?

Approximately 128 people will take part in this study at Cleveland Clinic.

What is involved if you decide to take part in this research study?

This study compares a standard pain relief regimen to a new pain relief regimen in patients sent home after gynecologic surgery.

On the day of your surgery, you will be randomized (like the flip of a coin) to one of two groups. Neither your doctor nor you can choose the treatment. It will be chosen by chance. One group of patients will be sent home with a standard pain regimen that includes non-opioid pain relievers and an opioid pain prescription. Another group of patients will be sent home with only non-opioid pain relievers, but they may request an opioid prescription if they desire one. After discharge from the hospital, all patients will have the option to request additional pain medications if they need it.

You will be asked to complete 3 brief questionnaires before your surgery. After your surgery, you will be asked to log your pain levels and pain medication use daily for 7 consecutive days beginning on post-op day 1. These logs can be completed electronically or with paper forms, depending on your preference. At your follow-up visit, you will be asked two questions about your satisfaction level with your pain relief regimen and your expectations about postoperative pain. Your participation in the research study will last about 6 weeks, starting at your preoperative visit and concluding at your postoperative follow-up visit.

You will receive periodic reminders to complete your pain medication and pain scale logs by text or email messages. You understand that by opting to receive text messages that standard carrier message rates may apply. Text and email messaging cannot be used to communicate medical information to your surgical team. You should delete these messages after the study period has completed, and you will be able to stop text messages at any time by replying 'STOP'.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

Taking part in this study is voluntary. The alternative is not to participate and to go home after surgery with the standard pain relief regimen.

3. RISKS

What are the risks of participating in the research study?

The main risks associated with this study are those related to postoperative pain. Some pain or discomfort is to be expected after urogynecologic surgery. You will receive multiple pain-reducing medications that may include non-opioid pain relievers and opioids. Your doctor and surgical team will ensure that your pain is being adequately controlled during your recovery.

Confidentiality Risks

There is a potential risk of loss of confidentiality of your data; however, your information will be de-identified and anonymous. Every effort will be made to keep your information confidential. The principal investigator will do her best to protect your privacy, including your personal identity and all personal medical information, will be maintained at all times. You will be identified not by your name, but by an identification code (identification number). We will store all data with a password protected database (REDCap) with unique identifiers that will protect

patient confidentiality. Only the study investigator and coordinators will have access to the data collected, which is protected for your confidentiality. This is further discussed below in the section entitled "Privacy and Confidentiality".

Use of Your Mobile Device to Receive Text Messages: Although every reasonable effort has been taken, confidentiality during text message communications cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others (third parties) not associated with this study. Data rates may apply.

Questionnaire/Survey Research

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

4. BENEFITS

What are possible benefits of participating in the research?

You may not receive direct benefit from being in this study. However, taking part in this study may help us to better understand how we can help manage postoperative pain in patients undergoing surgery in the future.

5. COSTS

Are there any costs to you if you participate in this study?

There are no direct costs to you for participation in the study. Most of the services you will receive during this research study **are considered to be conventional routine clinical services that you would have received even if you were not participating in the research** study and will be billed to you or your health insurance plan. Examples of these routine services include: The pre and post-operative surgical appointments, any surgical related costs, imaging or blood work. **You are responsible for paying any deductibles, copayments or co-insurance** that are a normal part of your health insurance plan.

6. PAYMENT

Are there any payments to you if you participate in this study?

Yes. You will receive $20 dollars upon completion of your daily patient logs, and $20 dollars at the completion of your postoperative visit. In addition, you will also be provided with a parking validation for use at your postoperative visit.

Completion of 7 day log:	$20
Postoperative visit:	$20
TOTAL	$40

The IRS requires CCF to report payments to an individual of $600 or greater (in a calendar year) on a Form 1099-MISC. Your name, address and social security number will be collected to track the payments made to you and, if you receive $600 or greater, will be used to process a Form 1099-MISC.

7. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?

In the event you suffer a research related injury as a result of being in this study, the costs for medical treatment may be billed to you or your medical insurance plan, if applicable. Medical insurance plans may or may not cover costs for medical treatment of research-related injuries. If you have insurance, you should check with your medical insurance plan before deciding to participate in this research study. In the event your medical insurance plan covers some or all of the treatment costs, you may still be responsible for co-pays or deductibles as required by your medical insurance plan.

Cleveland Clinic has not set aside any money to pay you or to pay for your treatment if you suffer a research related injury as a result of being in the study. There are no plans for Cleveland Clinic to provide other forms of compensation (such as lost wages, pain and suffering, or other direct or indirect losses) to you for research related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. Further information about research related injury is available by contacting the Institutional Review Board at (216) 444-2924.

8. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

Cleveland Clinic may share your study information, without anyone knowing that it is related to you specifically, with others or use it to research projects not listed in this form. Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

Study results may be shared in medical journals, at scientific meetings, and in other mediums without your identifying information. Your records will be confidential and your identity will not be shared in medical journals, at scientific meetings, and in other mediums without your express consent.

Authorization to Use/Disclose Protected Health Information

Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your

information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration) or safety monitors. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing**,** Cecile Ferrando, M.D., 9500 Euclid Ave. Desk A81, Cleveland, Ohio 44195**.** If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

A description of this clinical trial will be available on *http://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 the Website at any time.

9. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions or concerns about the research, or develop a research-related problem, you should contact Cecile Ferrando, M.D. at (216) 444-0642 during business hours. After hours, please contact the answering service at (216) 444-2200 and ask for the gynecologist on call. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

11. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date

_____
Printed name of Witness

_____ _____
Signature of Witness Date