THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER

Main Consent Form

TITLE: Prospective Study of Opioid Prescribing Practices in Laparoscopic Gynecologic Surgery

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1. KEY INFORMATION:

A person who takes part in a research study is called a research or study subject. In this consent form "you" refers to the research subject and/or the legally authorized representative.

You are being given the opportunity to participate in this research study. The purpose of this consent form is to help you decide if you want to be in the research study.

This study is comparing opioid prescribing practices by either 'standard" provider prescribing practices, or with the use of a 'calculator, ie., the Opioid Calculator, published by University of Michigan (**www.opioidcalculator.org**). A problem with the usual way of prescribing pain pills is that too many are prescribed and are frequently left over because the patient doesn't need them. The Opioid Calculator helps clinicians determine the number of pain pills the patient will actually need by taking into account age and other risk factors. The aim of the study is to determine if the use of calculator will result in prescribing enough pain pills to manage postoperative pain, without having a lot of pills left over that the patient doesn't need.

Procedures:
In this study, we will be collecting data from your medical record as clinical visits are completed. We will also be asking you to provide assessments of your pain level utilizing a pain rating scale (referred to as a Visual Analog Scale, VAS).

Subject Initials _____

In this study, we will randomize subjects between different treatment groups to evaluate the number of medication doses needed for appropriate pain control after laparoscopic gynecologic surgery.

You will be randomly assigned (like the flip of a coin) to receive post-operative pain medication according to 'standard' prescribing practices or according to the 'calculator'. You have a 1 in 2 chance of being prescribed pain medication according to either 'standard' prescribing practices or according to the 'calculator'. The investigator will not be the person who decides which group you will be assigned. A computer program that gives random numbers will be used to decide if you will be in the 'standard' group or in the 'calculator' group.

Your participation in this study will last through your post operative follow-up visit, which routinely takes place around 14 to 21 days after your surgery has been completed.

You will have 5 visits in total:

Visit 1	*Day 0 In person*	Review and sign consent for participation
Visit 2	*Day 1 In person*	Pre-operative: assess - level of pain Post-anesthesia: randomize to standard or calculator group Post-operative: assess - level of pain
Visit 3	*Day 2 telephone*	Assess - level of pain and number of pills taken
Visit 4	*Day 7 telephone*	Assess - level of pain and number of pills taken
Visit 5	*Day 14 to 21 In person*	Assess - level of pain Medication count of unused doses (bring unused pills to the visit, so they may be counted)

The following procedures are being performed for research purposes only:
The following procedures would NOT be performed if you were NOT participating in this study and are only being performed for research purposes only:

- Randomization to either the standard practice group or the opioid calculator group;
- Copying information such as your medical history, from your medical record;
- Telephone contacts specifically regarding post-operative pain on day 2 and day 7;
- One in person visit between Day 14 to 21 to assess pain level and physical count of unused pain medication.

For a detailed explanation of the procedures, refer to the section of this consent form entitled, DETAILED PROCEDURES TO BE FOLLLOWED.

Subject Initials _____

Risks:
You will be randomized to one of two groups that will be prescribed opioids for post operative pain management. The primary risks relate to receiving not enough pain pills or receiving too many pain pills. The risks of not receiving enough pain pills would be the inconvenience of needing to contact the doctor to prescribe more pills and the discomfort associated with ongoing pain in the absence of medication. The risks of prescribing too many pain pills are that the patient or other persons might use leftover pills in ways that would encourage or worsen someone's dependence on such drugs.

For a detailed list of the potential risks, refer to the section of this consent form entitled, RISKS ASSOCIATED WITH PARTICIPATION.

Benefits:
The results of this study may help people having laparascopic gynecologic surgery in the future by determining the appropriate number of pain pills needed to adequately control post-operative pain and prevent future over prescribing of pain medication.

Alternatives:
You will receive medical treatment for your gynecologic condition whether or not you participate in the study.

Voluntary Participation:
Your participation in this research study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Deciding to not take part in this research study will not change your regular medical care in any way.

If you are a student of the University of Tennessee, participating or not participating in this study will in no way influence your grade in any course. If you are a resident or fellow of the University of Tennessee, participating or not participating in this study will in no way influence your academic standing. If you are an employee of University of Tennessee participating or not participating in this study will not affect your employment status.

2. DETAILED PROCEDURES TO BE FOLLOWED:

Twelve (12) subjects will be participating in this study.

The study will take place at:
University of Tennessee Health Science Center Administrative

Obstetrics and Gynecology First Floor Rout Building 853 Jefferson Avenue, E102 & E149 Memphis, TN 38103	Data collection, transmission & storage.
Regional One Health – Outpatient Center Obstetrics and Gynecology Clinic 880 Madison Avenue, 3rd Floor Memphis, TN 38103	Clinical visits- examination, evaluation, consenting: creation of medical record information.
Regional One Health Chandler Bldg. - Surgery Center 877 Jefferson Avenue Memphis, TN 38103	Surgical Procedure and creation of medical record information

Using a computer-generated assignment, you will be randomized to either the 'standard' group or the 'calculator' group. After anesthesia is initiated on the day of surgery, a sealed randomization envelope will be opened with your assignment. You will not know to which group you are being assigned. Patients will be contacted on day 2 and day 7 to inquire where they are on the pain rating assessment Visual Analog Scale (VAS) and how many pills they have taken. Two weeks after surgery patients will be seen in the clinic office for a follow-up assessment on the VAS. You will requested to bring unused pills with you to this appointment for accounting purposes. The pills will be returned to you after they are counted.

Visit 1 (Day 0)

- Give informed consent at your routine doctor visit (this will take an additional 30-45 min)– for research purposes only;
- Information such as your age, weight, height, and medical history such as [previous heart attacks, etc.] will be copied from your medical record. Specifically, the following items will be collected: age, race ethnicity, insurance status (public vs. private), body mass index (BMI), depression, anxiety, prior chronic opioid use, history of alcohol abuse, history of chronic pain, and tobacco use. (this will take an additional 15-30min)– for standard of care and for research purposes;

Visit 2 (Day 1)

- Pre-operative assessment of current level of pain, (this will take an additional 5-10min)– for standard of care and for research purposes;
- Post-anesthesia randomization to standard or calculator group, (this will take an additional 5-10min)– for research purposes only;
- Post-operative assessment of current level of pain, (this will take an additional 5-10min)– for standard of care and for research purposes;

- Day of surgery, medical record information collection regarding details of surgical procedure, pain medication information to include: number of pills prescribed, number of pills used, opioid refill - requested or prescribed, (this will take an additional 30-45min)– for research purposes only;
- Day of surgery, prior to discharge, patients will be provided printed instructions that have been approved by Regional One Health for after care guidance with Total Laparoscopic Hysterectomy – standard of care;
- Day of surgery, prior to discharge, patients will be instructed to contact John Schorge, MD at 901-545-7345. This is a 24-hour/7-day telephone number located in the Labor and Delivery area of Regional One Health Hospital.

Visit 3 (Day 2)
- Telephone assessment of current level of pain and number of pills taken, (this will take 5-10min)– for research purposes;

Visit 4 **(**Day 7**)**
- Telephone assessment of current level of pain and number of pills taken, (this will take 5-10min)– for research purposes;

Visit 5 **(**Day 14 to 21)
- In person assessment of current level of pain,
- In person Medication count of unused doses,
- Collection of post operative pathology reports, (this will take an additional 15-30min)– for research purposes;

Your participation in this research study may be stopped by the study doctor without your consent for any of the following reasons:
- If you do not show up for visits
- If you do not follow the study doctor's instructions

If you decide to stop being part of the study, you should tell your study doctor, and any information that you have already provided will be kept in a confidential manner.

3. RISKS ASSOCIATED WITH PARTICIPATION:

There is a risk that your private identifiable information may be seen by people not involved in the research (such as if a researcher's computer is stolen or an electronic database is hacked). However, we will use very careful security measures (such as locks on file cabinets, computer passwords, etc.) to minimize the chance that any unauthorized persons might see your confidential information.

Subject Initials _____

All opioids share the side effects of sedation, dizziness, nausea, vomiting, constipation, physical dependence, tolerance, and respiratory depression. The most common side effects of opioid usage are constipation (which has a very high incidence) and nausea.

Risks related to receiving not enough pain pills or receiving too many pain pills: The risks of not receiving enough pain pills would be the inconvenience of needing to contact the doctor to prescribe more pills and the discomfort associated with ongoing pain in the absence of medication. The risks of prescribing too many pain pills are that the patient or other persons might use leftover pills in ways that would encourage or worsen someone's dependence on such drugs.

The research may involve risks to you which are currently unforeseeable. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

4. CONFIDENTIALITY:

Research records
All your paper research records will be stored in locked file cabinets and will be accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

All your electronic research records will be computer password protected and accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).
A master key/list which links your name with the code on your research record will be maintained at:

University of Tennessee Health Science Center
Obstetrics and Gynecology
First Floor Rout Building,
853 Jefferson Avenue, E149
Memphis, TN 38103

Your private information collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies.

Medical Records
Information about your participation in this study or the results of procedures performed in this study will be placed in your medical record. As such, it may be available to your

insurer. However, it will not be available to your employer, except with your explicit authorization and/or as permitted by law.

Presentations/Publications
While individual details about your case might be provided in publications or presentations about this research, they will not be discussed in a way that would allow you to be individually identified as a participant.

Limits to Confidentiality
Information obtained during the course of the study, which in the opinion of the investigator(s) suggests that you may be at significant risk of harm to yourself or others, may be reported to a third party to protect the rights and welfare of those at potential risk.

Authorization to Use and Disclose Protected Health Information for Research Purposes
Under federal privacy regulations, you have the right to decide who can review and copy your identifiable health information (called "protected health information" or PHI). PHI collected in this study may include information such as:

- Past and present medical records
- Records about your study visits
- Records about phone calls made as part of this research
- Research records

By signing this consent form, you are giving your permission for the study doctor and the study staff to get your PHI from your doctor and/or facilities where you have received health care. They may also share your PHI with:

- The Institutional Review Board (IRB) at the University of Tennessee Health Science Center
- Regional One Health

Your PHI will only be used and/or given to others:

- To do the research
- To study the results
- To see if the research was done correctly

Your PHI will be used until the study is completed.

You may withdraw or take away your permission to use and disclose your PHI at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you may not be able to stay in the study.

When you withdraw your permission, no new PHI will be gathered after that date. However, information that has already been gathered may still be used and given to others. The federal regulations allow you to review or copy your PHI that is used in this study.

However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. Once the study is over, your right to review and copy your PHI will be reinstated.

5. COMPENSATION AND TREATMENT FOR INJURY:

You are not waiving any legal rights or releasing the University of Tennessee, Regional One Health**,** or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and Regional One Health do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and Regional One Health do not provide for treatment or reimbursement for such injuries.

If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide acute medical treatment and will provide you with a subsequent referral to appropriate health care facilities.

If you are injured or get sick as a result of being in this study, you and/or your insurance will be billed for the costs associated with this medical treatment.

No compensation will be available to you for any extra expenses that you may have as the result of research-related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc.

No compensation will be available to you for any non-physical injuries that you may have as a result of research participation, such as legal problems, problems with your finances or job, or damage to your reputation.

6. QUESTIONS:

Contact John Schorge, MD at 901-448-2531 if you have questions about your participation in this study, or if you have questions, concerns, or complaints about the research.

If you feel you have had a research-related injury, contact John Schorge, MD at 901-545-7345. This is a 24-hour/7-day telephone number located in the Labor and Delivery area of Regional One Health Hospital.

Subject Initials _____

You may contact Cameron Barclay, MSA, UTHSC IRB Director, at 901-448-4824, or visit the IRB website at http://www.uthsc.edu/research/compliance/irb/ if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research.

7. PAYMENT FOR PARTICIPATION:

You will not be paid for participation in this research study.

Successful research using information about your health and your specimen (even if identifiers are removed) could result in commercial products, such as a drug to treat your disease. You will not share in any financial rewards associated with the development of these products.

8. COSTS OF PARTICIPATION:

There are no additional costs to you for participating in this study.

9. FUTURE CONTACT:

If we lose contact with you during the study for any reason (your phone number changes; your physical or email address changes; you are not responding to our attempts to contact you about your continued participation; etc.), we will attempt to find you or make contact with you in the following ways:

- The phone number(s) you provided to us will be called, but if you are not the person who answers, we will not say the title of the study or the fact that you are/were participating in a study.
- A letter will be sent to the address(es) you provided to us, but neither the return address nor any markings on the envelope will identify the title of the study or the fact that you are/were participating in a study.

Put your initials on one of the lines below:

_____We CAN attempt to find/contact you in the above ways.

_____We MAY NOT attempt to find/contact you in the above ways.

Subject Initials _____

10. CONSENT OF SUBJECT:

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

_____ _____ _____
Signature of Research Subject (18 years +) **Date** **Time**

_____
Printed Name of Adult Research Subject

_____ _____ _____
Signature of Person Obtaining Consent **Date** **Time**

_____
Printed Name of Person Obtaining Consent

In my judgment, the subject or the legally authorized representative has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____ _____ _____
Signature of Investigator **Date** **Time**