

**Evaluating the Effect of Preoperative Patient Education  
on Postoperative Opioid Consumption, Storage, and  
Disposal after Urogynecologic Procedures**

Protocol ID: 2017-11833

Study Protocol and Statistical Analysis Plan  
06/04/2018

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<b>Lead Researcher Name:</b> Kristen Buono MD	
<b>Study Title:</b> Evaluating the Effect of Preoperative Patient Education on Postoperative Opioid Consumption, Storage, and Disposal after Urogynecologic Procedures	

### CLINICAL TRIAL MASTER PROTOCOL AND INVESTIGATIONAL BROCHURE INFORMATION

	Master Protocol	Investigator Brochure:	Investigator Brochure:	Sponsor Consent Form Template(s)
Version #:				
Version Date:				
<p><b>[X]</b> This study is investigator-authored (investigator developed the study and is conducting the study at UCI and/or with other non-UCI sites).</p>				

### NON-TECHNICAL SUMMARY

Provide a brief non-technical summary or synopsis of the study that can be understood by IRB members with varied research backgrounds, including non-scientists and non-affiliated members.
<p>The purpose of this study is to evaluate whether providing patients with specialized preoperative counseling about the risks associated with opioid medications will lead to a reduction of opioid consumption after common urogynecologic surgeries. The study will be a randomized controlled trial that will be performed at two sites (UC Irvine Medical Center and Kaiser Permanente Orange County – Irvine Medical Center). Patients who agree to participate will be randomized to control (standard of care) arm or an intervention (specialized opioid education in the form of patient pamphlets and verbal scripts, which will be performed prior to their surgery and at the 2 week postoperative clinic visit) arm. The randomization will be stratified by medical facility. Assessment of the patients' opioid consumption will be conducted through physician-mediated pill counts during the patients' standardized postoperative clinic visits. Any additional opioid prescriptions within 12 months of the surgery will be evaluated by reviewing the patients' UC Irvine electronic medical records as well as the California</p>

Department of Justice's Controlled Substance Utilization Review and Evaluation System (CURES) 2.0 database. Additionally, patient pain scores and patients' current storage and disposal patterns of opioid medications will be evaluated through the use of questionnaires during standardized preoperative and postoperative clinic visits.

## **SECTION 1: PURPOSE AND BACKGROUND OF THE RESEARCH**

1. Provide the scientific or scholarly rationale for the research. Describe the relevant background information and the specific gaps in current knowledge that this study intends to address.

Morbidity and mortality from prescription opioid use is a rising epidemic within the United States.<sup>1</sup> The rates of substance abuse admissions and deaths attributable to prescription opioid abuse have significantly increased within the last ten years.<sup>2-4</sup> Unused postoperative opioid medications are a source of opioids that may ultimately be diverted or misused by someone other than the surgical patient. Recent research demonstrated that a significant proportion of patients do not dispose of excess opioid medication and have shared it with another person in the past.<sup>5</sup> Recent studies have sought to address the optimal postoperative opioid prescription in urologic, obstetrical, and general surgery.<sup>6-9</sup> In the literature to date, there is minimal data regarding normative patterns of postoperative oral opioid use amongst patients undergoing urogynecologic procedures. While early research demonstrates that physician education can significantly decrease postoperative opioid prescriptions,<sup>10</sup> there is a lack of data evaluating the effect of patient education on postoperative opioid consumption.

2. Provide relevant preliminary data (animal and/or human).

Hota et al. evaluated 57 women undergoing urogynecologic surgeries for pelvic organ prolapse and urinary incontinence and reported that the median number of opioid tablets consumed 2 weeks after a minimally invasive urogynecologic surgery was less than 10. Sixty six percent of patients reported having excess opioid tablets at 2 weeks postoperatively and 42% of patients reported that they were going to keep their excess tablets for future use.<sup>11</sup> Swenson et al. evaluated 50 patients who underwent minimally invasive urogynecologic surgery for the indication of pelvic organ prolapse and found that the median number of opioid tablets consumed was 13, and that participants only used one third of the amount prescribed.<sup>12</sup> Bates et al. surveyed adult patients who underwent surgery in a urology practice and showed that only 58% of the prescribed pain medication was used and 67% of participants reported having excess medication<sup>6</sup>. Of note, 92% of patients within the study reported receiving no formal disposal instructions for excess opioid medication and of those patients with leftover medication, 91% kept the medication at home. Bartels et al. found that 53% of participants reported taking fewer than five opioid tablets following a cesarean delivery.<sup>7</sup>

3. Describe the purpose, specific aims or objectives. Specify the hypotheses or research questions to be studied.

The purpose of this study would be to evaluate whether a preoperative educational pamphlet addressing the risks and side effects of opioid medications would reduce postoperative opioid consumption after common urogynecologic surgeries for the indication of pelvic organ prolapse. The hypothesis is that patients who receive the preoperative opioid education would consume less opioid tablets after their surgeries.

Additionally, the effect of the preoperative opioid educational intervention on postoperative patient storage patterns and compliance with FDA-recommended disposal patterns of opioid medications

would be evaluated. The hypothesis is that patients who receive the opioid education would have higher rates of safe storage patterns (out of sight, in a locked area) and FDA-recommended disposal patterns (return to a FDA-approved distribution center, mix with an unpalatable substance before disposing in the trash, or flushing down the sink or toilet) compared to patients who did not receive the opioid educational intervention.

The pattern of postoperative opioid consumption will be evaluated at 2 weeks and 6 weeks after the surgery and will be compared between subjects who underwent preoperative opioid education versus those who did not. The hypothesis is that subjects who receive the preoperative opioid education will be less likely to consume opioid tablets after 2 weeks compared to subjects who did not receive the educational intervention.

The rates of prescription refills 12 months after the surgery will be evaluated and compared between subjects who underwent preoperative opioid education versus those who did not. The hypothesis is that subjects who receive preoperative opioid education will be less likely to have opioid refills within the first 12 months postoperatively compared to subjects who did not receive the educational intervention.

The postoperative opioid consumption between subjects with particular clinical conditions (preoperative opioid use, active tobacco use, the presence of a chronic pain syndrome, anxiety, depression) will be compared to subjects without these conditions. The hypothesis is that subjects with these clinical conditions will have higher postoperative opioid consumption rates, including higher rates of opioid prescription refills within 12 months after surgery, compared to subjects without these conditions.

The subjects' opinions about the adequacy of their initial postoperative opioid prescriptions will be compared between subjects who received the preoperative educational intervention versus those who did not. The hypothesis is that subjects who received the preoperative educational intervention will be more likely to answer that their opioid prescription was "more than adequate" or "adequate" compared to subjects who did not receive the educational intervention. The subjects' opinions regarding the adequacy of their initial postoperative opioid prescriptions will be compared between subjects with particular clinical conditions (chronic pain syndromes, anxiety, depression, active tobacco use, and preoperative opioid use) to subjects without these conditions. The hypothesis is that subjects with the clinical conditions will be more likely to answer "less than adequate" regarding their postoperative opioid prescriptions compared to subjects without these clinical conditions.

4. Describe the primary outcome variable(s), secondary outcome variables, and predictors and/or comparison groups as appropriate for the stated study objectives/specific aims.

Primary outcome variable: mean number of opioid tablets consumed 2 weeks postoperatively

Secondary outcome variables:

1. Patient reported opioid consumption 6 weeks postoperatively
2. Modified surgical pain score (validated questionnaire) at the preoperative assessment and 2 weeks and 6 weeks postoperatively
3. Responses to the Preoperative Opioid Education Study Survey (investigator authored) at the preoperative assessment
4. Responses to the Postoperative Opioid Education Study Survey (investigator authored) at 2 weeks

and 6 weeks postoperatively

5. Evaluate the number of opioid prescription refills postoperatively within the UC Irvine electronic medical record system and California Department of Justice CURES 2.0 database at 2 weeks, 6 weeks, 12 weeks, and 12 months postoperatively
6. Evaluate intraoperative complications (packed red blood cell transfusion, bowel injury, bladder injury, ureteral injury, conversion to laparotomy) – each variable will be measured independently
7. Evaluate postoperative complications (mesh exposure, wound infection, packed red blood cell transfusion, neuropathy, or urinary tract infection within 6 weeks postoperatively or return to the operating room for within 14 days post operatively) – each variable will be measured independently
8. Total daily morphine equivalents prescribed in the hospital prior to discharge – to be calculated using the Opiate Equianalgesic Dosing Chart
9. Post-operative date upon discharge from the hospital
10. Post-operative date that the patient passed a voiding trial and the transurethral catheter was removed
11. Duration of the surgery (in minutes)

Comparison groups: subjects will be randomized to an intervention arm versus control arm. The intervention arm will receive opioid informational pamphlets in addition to the standard preoperative and postoperative instructions and counseling. The control arm will receive the current standard preoperative and postoperative instructions and counseling. The two arms will be stratified by study site (UC Irvine versus Kaiser Permanente Orange County – Irvine).

Additional analysis will be conducted to compare the modified surgical pain scores and answers to questions on the postoperative opioid education survey between subjects with preexisting clinical conditions (chronic pain syndromes, anxiety, depression, active tobacco use, and preoperative opioid use) as compared to subjects without these conditions.

5. List up to ten relevant references/articles to support the rationale for the research. Do not append an extensive NIH-grant-style bibliography.

1. Florence CS, Zhou C, Luo F, Xu L. The Economic Burden of Prescription Opioid Overdose, Abuse, and Dependence in the United States, 2013. *Med Care*. 2016;54(10):901-906.
2. Rudd RA, Seth P, David F, Scholl L. Increases in Drug and Opioid-Involved Overdose Deaths — United States, 2010–2015. *MMWR Morb Mortal Wkly Rep*. 2016;65(5051):1445-1452.
3. Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid pain relievers---United States, 1999--2008. *MMWR Morb Mortal Wkly Rep*. 2011;60(43):1487-1492.
4. Centers for Disease Control and Prevention (CDC). Vital signs: overdoses of prescription opioid pain relievers and other drugs among women--United States, 1999-2010. *MMWR Morb Mortal Wkly Rep*. 2013;62(26):537-542.
5. Kennedy-Hendricks A, Gielen A, McDonald E, McGinty EE, Shields W, Barry CL. Medication Sharing, Storage, and Disposal Practices for Opioid Medications Among US Adults. *JAMA Intern Med*. 2016;176(7):1027.
6. Bates C, Laciak R, Southwick A, Bishoff J. Trauma/Reconstruction/Diversion Overprescription of Postoperative Narcotics: A Look at Postoperative Pain Medication Delivery, Consumption and Disposal in Urological Practice. *J Urol*. 2011;185:551-555.
7. Bartels K, Mayes LM, Dingmann C, Bullard KJ, Hopper CJ, Binswanger IA. Opioid Use and Storage Patterns by Patients after Hospital Discharge following Surgery. *PLoS One*. 2016 Jan 29;11(1):e0147972
8. Bateman BT, Cole NM, Maeda A, et al. Patterns of Opioid Prescription and Use After Cesarean Delivery. *Obstet Gynecol*. 2017;130(1):29-35.
9. Hill M V, McMahon ML, Stucke RS, Barth RJ. Wide Variation and Excessive Dosage of Opioid Prescriptions for Common General Surgical Procedures. *Ann Surg*. 2016;265(4):1-6.
10. Hill M V., Stucke RS, McMahon ML, Beeman JL, Barth RJ. An Educational Intervention Decreases

Opioid Prescribing After General Surgical Operations. *Ann Surg.* 2017 Mar 6. doi: 10.1097/SLA.0000000000002198

11. Hota LS, Ward HA, Haviland MJ, et al. Opioid use following gynecologic and pelvic reconstructive surgery. *Int Urogynecol J* 2017 Sep 9. doi: 10.1007/s00192-017-3474-5

12. Swenson CW, Kelley AM, Fenner DE, Berger MB. Outpatient Narcotic Use After Minimally-Invasive Urogynecologic Surgery. *Female Pelvic Medicine & Reconstructive Surgery.* 2016;22(5):377-381.

## **SECTION 2: ROLES AND EXPERTISE OF THE STUDY TEAM**

1. List all research team members who will interact or intervene with human subjects or will have access to identifiable private information about human subjects.
2. For each research team member, indicate all applicable research activities the individual will perform.
3. If applicable, list the Faculty Sponsor as a Co-Researcher who will have research oversight responsibilities.

### **Lead Researcher:**

Name and Degree: Kristen Buono MD

Position/Title and Department:

Fellow, Female Pelvic Medicine and Reconstructive Surgery, Department of Obstetrics & Gynecology

Team Member will: ☒ Screen/Recruit ☒ Finalize Informed Consent

☒ Perform Research Activities ☒ Access subject identifiable data

List the research activities/procedures to be performed and the individual's relevant qualifications (training, experience):

Study design, identifying potential study participants, finalizing informed consent (reviewing, answering/asking questions, confirming competency, as necessary, and signing/confirming the informed consent), providing standardized patient education about opioid medications, administering patient questionnaires, quantifying remaining postoperative opioid tablets, collecting and organizing study patient documents, uploading study patient information into a secure data storage system, performing statistical analysis, and manuscript preparation.

Dr. Buono is a Female Pelvic and Reconstructive Surgery fellow at UC Irvine. She completed her obstetrics and gynecology residency at Kaiser Santa Clara, where she performed several research projects. She is an author on two scientific manuscripts in the literature to date.

### **Co-Researcher:**

Name and Degree: Taylor Brueseke MD

Position/Title and Department:

Assistant Professor, Female Pelvic Medicine and Reconstructive Surgery, Department of Obstetrics & Gynecology

Team Member will: ☒ serve as Faculty Sponsor with research oversight responsibilities

☒ Screen/Recruit ☒ Finalize Informed Consent

☒ Perform Research Activities    ☒ Access subject identifiable data

List the research activities/procedures to be performed and the individual's relevant qualifications (training, experience):

Study design, identifying potential study participants, finalizing informed consent (reviewing, answering/asking questions, confirming competency, as necessary, and signing/confirming the informed consent), providing standardized patient education about opioid medications, administering patient questionnaires, quantifying remaining postoperative opioid tablets, performing statistical analysis, and manuscript preparation.

Dr. Brueseke is an assistant professor within the division of Female Pelvic and Reconstructive Surgery (FPMRS) at UC Irvine. He completed his obstetrics and gynecology residency at UC Irvine and FPMRS fellowship at UNC Chapel Hill. He is an author on eleven scientific manuscripts in the literature to date, including five manuscripts as the first author.

**Co-Researcher:**

Name and Degree: Felicia Lane MD, MS

Position/Title and Department:

Vice Chair of Obstetrics & Gynecology Department, Division Director of Urogynecology

Team Member will: ☒ Screen/Recruit    ☒ Finalize Informed Consent

☒ Perform Research Activities    ☒ Access subject identifiable data

List the research activities/procedures to be performed and the individual's relevant qualifications (training, experience):

Study design, identifying potential study participants, finalizing informed consent (reviewing, answering/asking questions, confirming competency, as necessary, and signing/confirming the informed consent), providing standardized patient education about opioid medications, administering patient questionnaires, and quantifying remaining postoperative opioid tablets.

Dr. Lane is the division director of Female Pelvic and Reconstructive Surgery (FPMRS) at UC Irvine and vice chair of the department of Obstetrics & Gynecology at UC Irvine. She completed her obstetrics and gynecology residency and FPMRS fellowship at UC Irvine. She is an author on eighteen scientific manuscripts in the literature to date, including three manuscripts as the first author and five manuscripts as the final author.

**Co-Researcher:**

Name and Degree: Bhumy Davé, MD

Position/Title and Department:

Assistant Professor, Female Pelvic Medicine and Reconstructive Surgery, Department of Obstetrics & Gynecology

Team Member will: ☒ Screen/Recruit    ☒ Finalize Informed Consent

☒ Perform Research Activities    ☒ Access subject identifiable data

List the research activities/procedures to be performed and the individual's relevant qualifications (training, experience):

Study design, identifying potential study participants, finalizing informed consent (reviewing, answering/asking questions, confirming competency, as necessary, and signing/confirming the informed consent), providing standardized patient education about opioid medications, administering patient questionnaires, and quantifying remaining postoperative opioid tablets.

Dr. Davé is an assistant professor within the division of Female Pelvic and Reconstructive Surgery

(FPMRS) at UC Irvine. She completed her obstetrics and gynecology residency at Stanford University and FPMRS fellowship at Northwestern University. She is an author on five scientific manuscripts in the literature to date, including three manuscripts as the first author.

**Co-Researcher:**

Name and Degree: Neha Sudol, MD

Position/Title and Department:

Fellow, Female Pelvic Medicine and Reconstructive Surgery, Department of Obstetrics & Gynecology

Team Member will: ☒ Screen/Recruit ☒ Finalize Informed Consent

☒ Perform Research Activities ☒ Access subject identifiable data

List the research activities/procedures to be performed and the individual's relevant qualifications (training, experience):

Study design, identifying potential study participants, finalizing informed consent (reviewing, answering/asking questions, confirming competency, as necessary, and signing/confirming the informed consent), providing standardized patient education about opioid medications, administering patient questionnaires, and quantifying remaining postoperative opioid tablets.

Dr. Sudol is a Female Pelvic and Reconstructive Surgery fellow at UC Irvine. She completed her obstetrics and gynecology residency at NYU Medical Center. She is an author on three scientific manuscripts in the literature to date.

**Co-Researcher:**

Name and Degree: Sonia Dutta, MD

Position/Title and Department: Fellow, Female Pelvic Medicine and Reconstructive Surgery, Department of Obstetrics & Gynecology

Team Member will: ☒ Screen/Recruit ☒ Finalize Informed Consent

☒ Perform Research Activities ☒ Access subject identifiable data

List the research activities/procedures to be performed and the individual's relevant qualifications (training, experience):

Study design, identifying potential study participants, finalizing informed consent (reviewing, answering/asking questions, confirming competency, as necessary, and signing/confirming the informed consent), providing standardized patient education about opioid medications, administering patient questionnaires, and quantifying remaining postoperative opioid tablets.

Dr. Sudol is a Female Pelvic and Reconstructive Surgery fellow at UC Irvine. She completed her obstetrics and gynecology residency at Johns Hopkins University. She is an author on six scientific manuscripts in the literature to date, including four manuscripts as the first author.

**Research Personnel:**

Name and Degree: Elizabeth Lee

Position/Title and Department: Junior Specialist, Obstetrics & Gynecology

Research Assistant, Obstetrics & Gynecology Department

Team Member will: ☐ Screen/Recruit ☐ Finalize Informed Consent

☒ Perform Research Activities ☒ Access subject identifiable data



List the research activities/procedures to be performed and the individual's relevant qualifications (training, experience):

Administering patient questionnaires and quantifying remaining postoperative opioid tablets.

Elizabeth Lee is a research assistant within the department of Obstetrics and Gynecology at UC Irvine Medical Center. She graduated from UC Berkeley in 2017 and is in the process of applying to medical school.

### **SECTION 3: SUBJECT POPULATION(S) (INDIVIDUALS/RECORDS/SPECIMENS)**

#### **A. Subjects To Be Enrolled on this UCI protocol (Persons/Records/Biospecimens)**

1. Complete the table of subject enrollments below.
2. If the study involves the use of existing records or biological specimens, specify the maximum number to be reviewed/collected and the number needed to address the research question.

<b>Category/Group</b> (e.g., adults, controls, parents, children)	<b>Age Range</b> (e.g., 7-12, 13–17, adults)	<b>Maximum Number to be Consented or Reviewed/Collected</b> (include withdrawals and screen failures)	<b>Number Expected to Complete the Study or Needed to Address the Research Question</b>
Adults in intervention arm	18-99 years old	73	63
Adults in control arm	18-99 years old	73	63
		<b>Total: 146</b>	

#### **B. Overall Study Sample Size**

If this is a multi-site study, provide the total number of subjects to be enrolled from all sites.

Total number of subjects across all sites: 146

#### **C. Eligibility Criteria**

1. Identify the criteria for inclusion and exclusion.

Inclusion criteria:

Female

<p>Age 18-99 years old</p> <p>English speaking</p> <p>Evaluated by a provider within the Urogynecology division at UC Irvine or Kaiser Permanente Orange County – Irvine Medical Center and consented for either a uterosacral ligament suspension, sacrospinous ligament fixation, minimally-invasive colpopexy (either laparoscopic or robotic-assisted laparoscopic), colporrhaphy, or colpocleisis</p> <p>Exclusion criteria:</p> <p>Non English-speaking</p> <p>Cognitive deficits that would prevent the patient from completing the study questionnaires</p> <p>Cancellation of the surgery</p> <p>Combined case with another surgical service (i.e. colorectal surgery)</p>
<p>2. If eligibility is based on age, gender, pregnancy/childbearing potential, social/ethnic group, or language spoken (e.g., English Speakers only), provide a scientific rationale.</p>
<p>The division of urogynecology at UC Irvine exclusively treats female patients with the above stated procedures for the indication of pelvic organ prolapse. As such, male patients would not be eligible to participate since they are not candidates for the above noted procedures due to anatomical differences. The study patient educational pamphlets are only available in English and therefore the study objectives are best observed within an English proficient patient population.</p>

#### **SECTION 4: RECRUITMENT METHODS**

<p>Check any of the following methods that will be used to recruit subjects for this study:</p>
<p><input type="checkbox"/> This study involves no direct contact with subjects (i.e., use of existing records, charts, specimens).</p> <p>Specify database or IRB-approved protocol number (HS#), if applicable:</p>
<p><input type="checkbox"/> Advertisements, flyers, brochures, email, Facebook, and/or other media.</p> <p>Specify where recruitment materials will be posted:</p> <p>If subjects will be recruited by mail, e-mail, or phone, specify how their contact information will be obtained:</p>
<p><input type="checkbox"/> The study will be listed on <a href="https://clinicaltrials.gov">Clinicaltrials.gov</a>.</p>
<p><input type="checkbox"/> The study will be listed on the <a href="#">UC Irvine Health Clinical Trials</a> web page.</p>
<p><input type="checkbox"/> The <a href="#">UCI Social Sciences Human Subjects Lab/Sona Systems</a> will be used.</p>

<input type="checkbox"/> Referral from colleagues <ul style="list-style-type: none"> <li>Study team will provide colleagues with UCI IRB-approved recruitment materials for distribution to potential subjects (e.g., recruitment flyer, introductory letter);</li> <li>An IRB-approved recruitment letter will be sent by the <u>treating physician</u>. The letter will be signed by the treating physician and sent to his/her patients to inform them about how to contact study team members; and/or</li> <li>Colleagues obtain permission from interested patient to release contact information to researchers.</li> <li>Study team does not have access to patient names and addresses for mailing.</li> <li>If colleagues will screen their patients' medical records to determine subject eligibility and approach patients directly about study participation:</li> </ul>
<input type="checkbox"/> Study team will contact potential subjects who <i>have given prior permission to be contacted</i> for research studies.  Specify when and how these individuals granted permission for future contact:  Specify database or IRB-approved protocol number (HS#):
<input checked="" type="checkbox"/> Study team members will approach their own patients, students, employees for participation in the study.
<input type="checkbox"/> Study team will screen UCIMC medical records to which they have access to determine subject eligibility. The patients' physicians will approach patients directly about study participation.
<input type="checkbox"/> Other Recruitment Methods:

## **SECTION 5: INFORMED CONSENT PROCESS**

### **A. Methods of Informed Consent**

1. Indicate <u>all</u> applicable informed consent methods for this study.
<input checked="" type="checkbox"/> <b>Written (signed) informed consent will be obtained from subjects.</b> Signed informed consent, parental permission, and/or child assent will be obtained from subjects, as applicable.
<input type="checkbox"/> <b>Requesting a waiver of written (signed) informed consent.</b> Signed consent will not be obtained; consent will be obtained verbally or via the web. Informed consent, parental permission and/or child assent will be obtained from subjects, as applicable.
<input type="checkbox"/> <b>Requesting to seek surrogate consent from a legally authorized individual.</b> Surrogate consent may be considered <u>only</u> in research studies relating to the cognitive impairment, lack of capacity or serious or life-threatening disease and conditions of the research subjects.
<input type="checkbox"/> <b>Requesting a waiver of informed consent.</b> (i.e., consent will not be obtained).

2. Indicate where the consent process will take place.
<input checked="" type="checkbox"/> In a private room <input type="checkbox"/> In a waiting room <input type="checkbox"/> In an open unit <input type="checkbox"/> In a group setting <input type="checkbox"/> The internet <input type="checkbox"/> In public setting <input type="checkbox"/> Over the phone <input checked="" type="checkbox"/> Other (specify): In a private patient setting within a preoperative unit
3. Specify how the research team will assure that subjects have sufficient time to consider whether to participate in the research.
<input checked="" type="checkbox"/> Subjects will be allowed to take home the unsigned consent form for review prior to signing it.  <input checked="" type="checkbox"/> Other (specify): The study protocol will be introduced to the patient at either the consultation visit, preoperative clinic visit, or in the preoperative unit prior to surgery. If a patient is undecided about whether she would like to participate at the consultation or preoperative visit, the study will be readdressed at the next clinical interaction (which is normally at least a 2 week interval). If the initial discussion of the study protocol occurs in the preoperative unit and the patient is undecided, she will be given a minimum of 15 minutes to reconsider and discuss with family members before a second discussion is conducted.
4. If children are enrolled in this study, describe the parental permission process and the child assent process.
<input checked="" type="checkbox"/> Not applicable: Children are not enrolled in this study.
5. Some subjects may be vulnerable to coercion or undue influence, such as those who are economically or educationally disadvantaged, mentally disabled, or students (undergraduate, graduate, and medical students) and employees of UCI (administrative, clerical, nursing, lab technicians, post-doctoral fellows and house staff, etc.), describe the procedures to ensure the voluntary participation of these individuals.
<input checked="" type="checkbox"/> Not applicable: Subjects are not vulnerable to coercion or undue influence due to the lack of financial compensation for study subjects.  <input checked="" type="checkbox"/> Other (specify): If a patient refuses study participation during either the first or second discussion (if she was originally undecided after the first discussion), it will be honored. The patients will be reassured that their decision to not participate in the study will not influence their medical care.

**B. Health Insurance Portability and Accountability Act (HIPAA) Authorization**

Indicate <u>all</u> applicable HIPAA authorization methods for this study.
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- ☐ Not applicable: Study does not involve the creation, use, or disclosure of [Protected or Personal Health Information \(PHI\)](#).
- ☐ **Requesting a Total waiver of HIPAA Authorization.** HIPAA authorization will not be obtained at all for the study.
- ☐ **Requesting a Partial waiver of HIPAA Authorization.** HIPAA authorization will not be obtained for screening/recruitment purposes. However, written (signed) HIPAA research authorization is obtained for further access to personal health information.
- ☒ **Written (signed) HIPAA Research Authorization will be obtained from subjects.** Signed authorization, parental authorization, and/or child assent will be obtained from subjects, as applicable.

### C. Methods of Informed Consent for non-English Speakers

1. Indicate the applicable informed consent method for non-English speakers.

- ☒ Not applicable: Only individuals who can read and speak English are eligible for this study.
- ☐ The English version of the consent form will be translated into appropriate languages for non-English speaking subjects once IRB approval is granted.
- ☐ Requesting a short form consent process.  
The short form process will be used for the following occasional and unexpected languages:
  - ☐ All non-English languages
  - ☐ All non-English languages except Spanish
  - ☐ Other languages (specify):

2. Explain how non-English speaking subjects will be consented in their language and who will be responsible for interpreting and facilitating the informed consent discussion for the non-English speaking subjects.

- ☐ At least one member of the study team is fluent in the language that will be used for communication, and that study team member(s) will be available during emergencies.
- ☐ The study team has 24-hour access to a translation service with sufficient medical expertise to discuss the research in this study.
- ☐ Other (explain):

## **SECTION 6: RESEARCH METHODOLOGY/STUDY PROCEDURES**

### **A. Study Location**

Specify where the research procedures will take place (e.g. UCI Douglas Hospital – Cardiac Care Unit, UCI Main Campus Hewitt Hall, UCI Health – Pavilion II, UCI Family Health Center, Anaheim, Irvine High School).

UCI Douglas Hospital – Preoperative Unit  
UCI Medical Center Manchester Building – Women’s Clinic  
Kaiser Permanente Orange County – Irvine Medical Center – Preoperative Unit  
Kaiser Permanente Orange County – Irvine Medical Center – Obstetrics and Gynecology Clinic

### **B. Study Design**

1. Include an explanation of the study design (e.g., randomized placebo-controlled, cross-over, cross-sectional, longitudinal, etc.) and, if appropriate, describe stratification/ randomization/blinding scheme.

Randomized, non-blinded, controlled trial. Patients will be randomized into intervention (specific patient opioid education performed) and control (standard of care without specific patient opioid education) arms through a randomization scheme in REDCap. Randomization will be stratified by medical center (UC Irvine Medical Center versus Kaiser Permanente Orange County – Irvine Medical Center). Patients and providers will not be blinded due to the nature of the intervention (educational).

2. Provide precise definitions of the study endpoints and criteria for evaluation; if the primary outcomes are derived from several measurements (i.e., composite variables) or if endpoints are based composite variables, then describe precisely how the composite variables are derived.

Primary outcome: mean number of opioid tablets consumed 2 weeks postoperatively

Secondary outcome variables:

1. Patient reported opioid consumption 6 weeks postoperatively
2. Modified surgical pain score (validated questionnaire) at the preoperative assessment and 2 weeks and 6 weeks postoperatively
3. Responses to the Preoperative Opioid Education Study Survey (investigator authored) at the preoperative assessment
4. Responses to the Postoperative Opioid Education Study Survey (investigator authored) at 2 weeks and 6 weeks postoperatively
5. Evaluate the number of opioid prescription refills postoperatively within the UC Irvine electronic medical record system and California Department of Justice CURES 2.0 database at 2 weeks, 6 weeks, 12 weeks, and 12 months postoperatively
6. Evaluate intraoperative complications (packed red blood cell transfusion, bowel injury, bladder injury, ureteral injury, conversion to laparotomy) – each variable will be measured independently
7. Evaluate postoperative complications (mesh exposure, wound infection, packed red blood cell transfusion, neuropathy, or urinary tract infection within 6 weeks postoperatively or return to the operating room for within 14 days post operatively) – each variable will be measured independently
8. Total daily morphine equivalents prescribed in the hospital prior to discharge – to be calculated using the Opiate Equianalgesic Dosing Chart
9. Post-operative date upon discharge from the hospital

10. Post-operative date that the patient passed a voiding trial and the transurethral catheter was removed
11. Duration of the surgery (in minutes)

### C. Research Procedures

1. Provide a detailed chronological description of all research procedures.

The study concept would be introduced to the patients at the consult visit, preoperative visit, on in the preoperative unit prior to surgery. If the patient agrees to participation during any of these encounters, written consent and HIPPA authorization will be obtained and the patient would be randomized to the intervention or control arm using a computerized randomization scheme on REDCap. The randomization will be stratified by the site of the surgery (UC Irvine Medical Center versus Kaiser Permanente Orange County – Irvine Medical Center). If the patient is randomized to the intervention arm, the first opioid informational pamphlet will be provided and reviewed with the patient in addition to standard preoperative instructions. If the patient is randomized to the control arm, standard preoperative instructions will be provided. Patients within both arms of the study will receive standardized postoperative medication prescriptions prior to the surgery. Patients within both arms of the study will complete the modified surgical pain score and preoperative opioid education study survey prior to surgery.

After the surgery is completed, the primary surgeon will decide whether to admit the patient to the hospital and which postoperative analgesics will be administered within the hospital prior to discharge for subjects in both study arms. The patient will follow up for standard postoperative clinic visits at 2 weeks and 6 weeks postoperatively. One to two days prior to the 2 week postoperative visit, the patient will be contacted via telephone to remind her to bring her opioid prescription bottle to the clinic visit.

Between the surgery date and the 2 week postoperative visit, the electronic medical records will be reviewed to evaluate the length of the surgery, intraoperative complications, the postoperative date of discharge, the postoperative date of removal of the transurethral foley catheter, the total daily morphine equivalents that the patient was prescribed prior to discharge from the hospital, and the presence of opioid prescriptions 30 days prior to the surgery. Additionally, the CURES 2.0 Database will be queried to evaluate for opioid prescriptions 30 days prior to the surgery.

During the 2 week postoperative visit, the remaining opioid tablets will be counted and recorded by a co-investigator. The patient will complete the modified surgical pain score and postoperative opioid education study survey. The UC Irvine electronic medical record system and CURES 2.0 Database will be queried to evaluate for additional opioid prescriptions since the time of surgery. Patients randomized to the intervention arm will receive the second opioid informational pamphlet, which will be reviewed by a co-investigator.

During the 6 week postoperative visit, the patient will complete the modified surgical pain score and postoperative opioid education study survey. The UC Irvine electronic medical record system and CURES 2.0 Database will be queried to evaluate for additional opioid prescriptions since the time of surgery. The patients' electronic medical records will be reviewed after the 6 week postoperative visit to evaluate for postoperative complications.

Twelve weeks after the surgery, the UC Irvine electronic medical record system and CURES 2.0 Database will be queried to evaluate for additional opioid prescriptions since the time of surgery.

If a patient fails to follow up for a postoperative visit, at least two attempts will be made to contact the patient via telephone to collect opioid pill counts and have the patient verbally complete the modified

surgical pain score and postoperative opioid education study survey. Initial statistical analysis will be performed after the 12 week postoperative opioid refill assessment

Twelve months after the surgery, the UC Irvine electronic medical record system and CURES 2.0 Database will be queried to evaluate for additional opioid prescriptions since the time of surgery. Additional statistical analysis will be performed after the 12 month opioid refill prescriptions have been evaluated.

While this is a multi-site trial involving subjects from UC Irvine and Kaiser Permanente Orange County – Irvine, only deidentified data will be uploaded into the REDCap data management system. The lead investigator will maintain a separate key containing patient health information for subjects from both sites, which will be utilized to evaluate for additional opioid prescriptions 12 months after the surgery. Co-investigators from both study sites will not have access to identifiable data from subjects that were not recruited from their particular study site.

2. Describe the duration of a subject's participation in the study. If there are sub-studies, include duration of participation in each sub-study.

Each study subject will actively participate within the study from the time of consent through the 6 week post operative visit, which will last between 3-6 months. Study subjects' electronic medical records will be reassessed 12 weeks and 12 months after the surgery but subjects will not be directly contacted or actively participate in the study at this time.

3. List data collection instruments (e.g., measures, questionnaires, interview questions, observational tool, etc.).

Modified Surgical Pain Score – Validated

Preoperative Opioid Education Study Survey – Investigator-authored

Postoperative Opioid Education Study Survey – Investigator-authored

#### **D. UCIMC Supplementary Clinical Services**

If a UCIMC clinical unit/department (e.g., phlebotomy for blood draws, pharmacy for dispensing study drug(s), radiation services for X-rays, MRIs, CT scans, and Neurology for lumbar punctures) will perform research-related procedures:

1. List the research procedure (e.g. lumbar puncture, MRI, CT Scan), and
2. Identify the unit/department that will perform the procedure.

**[X]** Not applicable: This study does not involve the services of a UCIMC clinical unit/department.

#### **E. Privacy**

Privacy is about the subject's ability to control how much others see, touch, or collect information about the subject. Indicate all of the following methods that will be used to assure subject privacy.



- ☒ Research procedures (including recruitment) are conducted in a private room.
- ☐ Use of drapes or other barriers for subjects who are required to disrobe.
- ☒ Only sensitive information directly related to the research is collected about subjects.
- ☐ When information is collected from internet sources, the internet site's privacy statement will be reviewed and followed.
- ☐ Other (specify):

#### F. Use of Existing Biological Specimens and/or Existing Information/Data

1. For studies that involve use of existing (i.e. on the shelf; currently available) specimens:
  - a. Indicate the source of the specimens and whether the specimens were originally collected for research purposes.
  - b. Explain how the existing specimens will be obtained.

☒ Not applicable: This study does not involve use of existing biological specimens.

**Source: Indicate all that apply:**

☐ UCI/UCIMC

Originally collected for research purposes: ☐ YES; UCI IRB number (i.e. HS#):

☐ NO; explain:

☐ UCIMC Pathology Biorepository will provide specimens.

☐ Non-UCI Entity; specify:

Originally collected for research purposes: ☐ YES ☐ NO; explain:

☐ Other; explain:

2. For studies that involve use of existing (i.e. on the shelf; currently available) clinical data:
  - a. Specify the source of the clinical data.
  - b. Explain how the study team will access the clinical data.

☐ Not applicable: This study does not involve use of existing clinical data.

**Source: Indicate all that apply:**

☒ UCI/UCIMC.

☐ non-UCI Entity; specify:

**How Obtained: Indicate all that apply:**

☐ The study team will request specific patient information/data from UCIMC Health Information Management Services.

☒ The study team will review their patients' records and abstract data directly from those records.

☐ The study team will request specific patient information/data from UCI Health Honest Broker Services. Describe the following:

Cohort selection criteria (e.g., use the available Clinical Terms from the Cohort Discovery Tool such as Demographics: Gender, Diagnoses: Asthma, Procedures: Operations on digestive system):

Expected cohort size/patient count:

Cohort attributes or data elements (e.g., lab test values, medication, etc.):

☐ Other; explain:

3. For studies that involve use of existing (i.e. on the shelf; currently available) clinical data, specify the time frame of the clinical data to be accessed (e.g. records from January 2002 to initial IRB approval).

Data will be collected on subjects enrolled in the study after IRB approval

## **G. Collection of Photographs, or Audio/Video Recording**

1. Describe all procedures involving the use and/or collection of photographs, or audio/video recording.

☒ Not applicable: This study does not involve photographs or audio/video recording.

2. Specify if photographs or audio/video recording will include subject identifiable information (e.g., name, facial image). If so, indicate which identifiers will be collected.

N/A

3. Explain whether the photographs or audio/video recording will be included in subsequent presentations and/or publications and, if so, whether subject identifiers will be included.

N/A

## H. Sharing Results with Subjects

1. Describe whether individual results (results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subject or others (e.g., the subject's primary care physician).
2. Explain what information will be shared and how the results will be shared.

☒ Not applicable: Individual results will not be shared with subjects.

3. Describe whether overall study results will be shared with subjects.
4. Explain how results will be shared.

☒ Not applicable: Final study results will not be shared with subjects.

## I. Statistical Considerations

1. Statistical Analysis Plan: Describe the statistical method(s) for the stated specific aims and hypotheses. *Your analysis plans should match the stated study specific aims and hypotheses in Section 1.*

☐ Not applicable: A statistical analysis plan is not appropriate for this qualitative study design. Plan for assessing study results:

2. Describe the primary statistical method(s) that will be used to analyze the primary outcome(s) or endpoints.

A t-test will be used to analyze the primary outcome, which will compare the mean number of opioid tablets consumed by subjects in the two study arms.

3. Describe the secondary statistical method(s) that will be used to analyze the secondary outcome(s) or endpoints.

A t-test will be used to compare the mean number of opioid tablets consumed at 6 weeks and 12 weeks postoperatively between subjects in the two study arms. A t-test will be used to compare the modified surgical pain score answers between subjects in the two study arms at the preoperative assessment, 2 weeks postoperatively, and 6 weeks postoperatively. Fisher's exact test will be used to compare the subjects' answers to standardized questions on the preoperative and postoperative opioid education study surveys (categorical response variables) between the two study arms. A Mann-Whitney test will be used to compare the number of opioid prescription refills at 2 weeks, 6 weeks, 12 weeks, and 12 months postoperatively between subjects in the two study arms. A Fisher exact test will be used to compare the rates of intraoperative and postoperative complications between subjects in the two study arms. A t-test will be used to compare the length of time to postoperative discharge, time to postoperative foley catheter removal, and length of the surgery between subjects in the two study

arms.
4. If appropriate describe secondary or post hoc analyses of primary outcome(s) or other exploratory analysis.
N/A
5. Sample Size Determination: Explain how the overall target sample size was determined (e.g., power analysis; precision estimation), providing justification of the effect size for the primary outcome based on preliminary data, current knowledge/literature and/or cost consideration; if appropriate, provide sample size justification for secondary outcomes. Power analysis should (at least) match the primary outcome/endpoint.
A power calculation indicates that a sample size of 63 subjects in each arm is necessary to achieve 80% power to detect a mean difference of 5 opioid tablets consumed with a significance level of 0.05. This difference is equivalent to a difference of 0.5 SD. Given an anticipated attrition rate of 15%, 73 subjects will be recruited into each arm of the study. Current literature suggests that the mean number of opioid tablets consumed by patients undergoing urogynecologic surgeries for pelvic organ prolapse ranges between 2-13 tablets and therefore, this study is powered to detect a 50% decrease in postoperative opioid tablet consumption if we anticipate that patients who do not undergo the educational intervention will consume a mean of 10 tablets.

## **SECTION 7: RISK ASSESSMENT AND POSSIBLE BENEFITS**

### **A. Risk Assessment**

1. Indicate the appropriate level of review of this study, based upon your risk assessment.
<input type="checkbox"/> This study involves greater than minimal risk to subjects and requires Full Committee review. <input checked="" type="checkbox"/> This study involves no more than minimal risk and qualifies as <a href="#">Expedited research</a> .
2. If this study involves no more than minimal risk, provide justification for the level of review <u>and</u> for all applicable Expedited Categories you have chosen.
<p>This study involves the use of educational pamphlets and patient questionnaires, neither of which constitutes more than minimal risk for the patient. The decision to proceed with surgical intervention, as well as the choice of which surgery the subject undergoes, will be decided between the subject and primary surgeon prior to enrollment in the study. This particular study qualifies under the Expedited Category 7, which refers to research on individual or group characteristic or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Additionally, this study qualifies under Category 5 of expedited review, as it entails a review of medical information, collected as part of clinical care, and not collected specifically for this protocol.</p>

## B. Risks and Discomforts

1. Describe and assess any reasonably foreseeable risks and discomforts — physical, psychological, social, legal or other. Include an assessment of their expected frequency (e.g., common – 65%, less common – 40%, unlikely – 5%, rare – <1%) and the seriousness (mild, moderate, severe).

Risks of the educational intervention of the study:

- Anxiety – unlikely (5%), mild
- Psychological harm (embarrassment) – unlikely (5%), mild
- Potential breach of confidentiality – rare (<1%), moderate

2. Discuss what steps have been taken and/or will be taken to prevent and minimize any risks/potential discomforts to subjects.

The primary intervention in this study is an educational intervention and is associated with minimal risk to the study subjects. Patients will have the opportunity to complete their preoperative and postoperative questionnaires in a private room, which helps reduce the risk of anxiety or psychological harm. Security provisions to protect confidential patient information will include the use of encrypted emails, password-protected data storage systems and storage of patient paper files in a locked room.

## C. Potential Benefits

1. Describe the potential benefits subjects may expect to receive from participation in this study.

[ ] There is no direct benefit anticipated for the subjects.

Patients in the intervention arm will learn about appropriate storage and disposal patterns of opioid medications. Additionally, they will learn about side effects of opioid medications that they might not have otherwise been aware of. Conceivably any intervention that leads to a reduction of opioid consumption after surgery would help minimize the side effect profile and risks associated with these medications.

2. Specify the expected potential societal/scientific benefit(s) of this study.

The rates of substance abuse admissions and deaths attributable to prescription opioid abuse have significantly increased within the last ten years. Unused postoperative opioid medications are a source of opioids that may ultimately be diverted or misused by someone other than the surgical patient. The current literature indicates that a significant proportion of postoperative patients do not dispose of excess opioid medication and have even shared it with another person in the past. Educating surgical patients about the risks associated with opioid medications may help reduce opioid consumption, which has beneficial cost implications to society (reduced postoperative emergency room visits or urgent clinic visits). Educating surgical patients about appropriate storage and disposal of unused opioid medications would reduce the risk of opioid diversion to others who may be more likely to abuse these medications. Improved counseling of postoperative patients presents an opportunity to reduce opioid consumption and improve appropriate disposal of unused medications, both of which are beneficial for the society at large.

## **SECTION 8: ALTERNATIVES TO PARTICIPATION**

Describe the alternatives to participation in the study available to prospective subjects. Include routine (standard of care) options as well as other experimental options, as applicable.

☒ No alternatives exist. The only alternative to study participation is not to participate in the study.

☐ There are routine standard of care alternatives available; specify:

☐ There are other alternatives to study participation; specify:

## **SECTION 9: SUBJECT COSTS**

1. Indicate below if subjects or their insurers will be charged for study procedures. Identify and describe those costs.

☐ Not applicable: This study involves no interaction/intervention with research subjects.

☒ This study involves interaction/intervention with research subjects; however there are no costs to subjects/insurers. The study interventions are being performed during standard preoperative and postoperative clinic visits that would have occurred even if the subject was not enrolled in the study.

☐ This study involves interaction/intervention with research subjects, and there are costs to subjects/insurers:

2. If subjects or their insurers will be responsible for study-related costs, explain why it is appropriate to charge those costs to the subjects or their insurers. Provide supporting documentation as applicable (e.g., study procedures include routine (standard of care) procedures; FDA IDE/HDE/IND letter that supports billing to subjects).

☒ Not applicable: The study involves no costs to subjects for study participation.

☐ Study related costs will be billed to subjects or their insurers for the following reasons:

## **SECTION 10: SUBJECT COMPENSATION AND REIMBURSEMENT**

1. If subjects will be compensated for their participation, explain the method/terms of payment (e.g., money; check; extra credit; gift certificate).

<p><input type="checkbox"/> Not applicable: This study involves no interaction/intervention with research subjects.</p> <p><input checked="" type="checkbox"/> No compensation will be provided to subjects.</p> <p><input type="checkbox"/> Compensation will be provided to subjects in the form of cash/gift certificate.</p> <p><input type="checkbox"/> Compensation will be provided to subjects in the form of a check issued to the subjects through the UCI Accounting Office. The subject's name, address, and social security number, will be released to the UCI Accounting Office for the purpose of payment and for tax reporting to the Internal Revenue Service (IRS).</p> <p><input type="checkbox"/> Other:</p>
<p>2. Specify the schedule and amounts of compensation (e.g., at end of study; after each session/visit) including the total amount subjects can receive for completing the study.</p>
<p><input checked="" type="checkbox"/> Not applicable: This study involves no compensation to subjects.</p> <p>Subjects will be compensated with the following schedule and amounts:</p>
<p>3. Specify whether subjects will be reimbursed for out-of pocket expenses. If so, describe any requirements for reimbursement (e.g., receipt).</p>
<p><input checked="" type="checkbox"/> Not applicable: This study involves no reimbursement to subjects.</p> <p>Subjects will be reimbursed; specify:</p>

## **SECTION 11: CONFIDENTIALITY OF RESEARCH BIOSPECIMENS/DATA**

### **A. Biospecimens/Data Storage**

<p>1. Indicate all subject identifiers that may be included with the biospecimens or collected for the research study.</p>																					
<p><input type="checkbox"/> This study does not involve the collection of subject identifiers.</p> <p>Check all the following subject identifiers will be used, created, collected, disclosed as part of the research:</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 33%;"><input checked="" type="checkbox"/> Names</td> <td style="width: 33%;"><input type="checkbox"/> Social Security Numbers</td> <td style="width: 33%;"><input type="checkbox"/> Device identifiers/Serial numbers</td> </tr> <tr> <td><input checked="" type="checkbox"/> Dates</td> <td><input checked="" type="checkbox"/> Medical record numbers</td> <td><input type="checkbox"/> Web URLs</td> </tr> <tr> <td><input checked="" type="checkbox"/> Postal address</td> <td><input type="checkbox"/> Health plan numbers</td> <td><input type="checkbox"/> IP address numbers</td> </tr> <tr> <td><input checked="" type="checkbox"/> Phone numbers</td> <td><input type="checkbox"/> Account numbers</td> <td><input type="checkbox"/> Biometric identifiers</td> </tr> <tr> <td><input type="checkbox"/> Fax numbers</td> <td><input type="checkbox"/> License/Certificate numbers</td> <td><input type="checkbox"/> Facial Photos/Images</td> </tr> <tr> <td><input type="checkbox"/> Email address</td> <td><input type="checkbox"/> Vehicle id numbers</td> <td><input type="checkbox"/> Any other unique identifier</td> </tr> <tr> <td colspan="3"><input type="checkbox"/> Other (Specify all):</td> </tr> </table>	<input checked="" type="checkbox"/> Names	<input type="checkbox"/> Social Security Numbers	<input type="checkbox"/> Device identifiers/Serial numbers	<input checked="" type="checkbox"/> Dates	<input checked="" type="checkbox"/> Medical record numbers	<input type="checkbox"/> Web URLs	<input checked="" type="checkbox"/> Postal address	<input type="checkbox"/> Health plan numbers	<input type="checkbox"/> IP address numbers	<input checked="" type="checkbox"/> Phone numbers	<input type="checkbox"/> Account numbers	<input type="checkbox"/> Biometric identifiers	<input type="checkbox"/> Fax numbers	<input type="checkbox"/> License/Certificate numbers	<input type="checkbox"/> Facial Photos/Images	<input type="checkbox"/> Email address	<input type="checkbox"/> Vehicle id numbers	<input type="checkbox"/> Any other unique identifier	<input type="checkbox"/> Other (Specify all):		
<input checked="" type="checkbox"/> Names	<input type="checkbox"/> Social Security Numbers	<input type="checkbox"/> Device identifiers/Serial numbers																			
<input checked="" type="checkbox"/> Dates	<input checked="" type="checkbox"/> Medical record numbers	<input type="checkbox"/> Web URLs																			
<input checked="" type="checkbox"/> Postal address	<input type="checkbox"/> Health plan numbers	<input type="checkbox"/> IP address numbers																			
<input checked="" type="checkbox"/> Phone numbers	<input type="checkbox"/> Account numbers	<input type="checkbox"/> Biometric identifiers																			
<input type="checkbox"/> Fax numbers	<input type="checkbox"/> License/Certificate numbers	<input type="checkbox"/> Facial Photos/Images																			
<input type="checkbox"/> Email address	<input type="checkbox"/> Vehicle id numbers	<input type="checkbox"/> Any other unique identifier																			
<input type="checkbox"/> Other (Specify all):																					

Indicate how data will be stored and secured, including electronic data as well as hardcopy data paper records, electronic files, audio/video tapes, biospecimens, etc.

**Electronic Data/Files (check all that apply):**

- ☐ Anonymous data will be maintained; no subject identifiers
- ☒ Coded data; code key is kept separate from data in secure location.
- ☐ Data includes subject identifiable information. Provide rationale for maintaining subject identifiable info):
- ☒ Data will be stored on secure network server.
- ☐ Data will be stored on standalone desktop computer (not connected to network/internet)
- ☐ Other (specify here):

**Hardcopy Data (Records, Recordings, Photographs) and Biospecimens (check all that apply):**

- ☐ Anonymous biospecimens/data will be maintained; no subject identifiers
- ☒ Coded data; code key is kept separate from biospecimens/data in secure location.
- ☐ Biospecimens/Data includes subject identifiable information (Provide rationale for maintaining subject identifiable info):
- ☒ Data will be stored in locked file cabinet or locked room.
- ☐ Biospecimens will be stored in locked lab/refrigerator/freezer.
- ☐ Other (specify here):

2. List the location(s) where the data and/or biological specimens will be stored.

Data will be stored within file cabinets in locked rooms (offices of the co-investigators) at the UC Irvine Women's Clinic and Kaiser Permanente Orange County – Irvine Medical Center OB Gyn Clinic.

3. If subject identifiable data will be transported or maintained on portable devices, explain why it is necessary use these devices.

☒ Not applicable: Research data will not be transported or maintained on portable devices.

Research data will need to be maintained on the following portable device(s) for the following reason(s):

**B. Data and/or Biological Specimens Access**

Specify who will have access to subject identifiable data and/or biological specimens as part of this study.



☐ Not applicable: No subject identifiers will be collected.

☒ Authorized UCI personnel such as the research team and appropriate institutional officials, the study sponsor or the sponsor's agents (if applicable), and regulatory entities such as the Food and Drug Administration (FDA), the Office of Human Research Protections (OHRP), and the National Institutes of Health (NIH).

☐ Other:

### C. Data and/or Biological Specimens Retention

Indicate how long subject identifiable data and/or biological specimens, including the subject code key will be retained.

☐ Not applicable: No subject identifiable research data will be retained.

☒ Separate code key will be destroyed or subject identifiable information will be removed from the biospecimens and/or data at the earliest convenience, consistent with the conduct of this research. Specify timeframe: Code key will be destroyed after the subjects have been identified within the UC Irvine electronic medical system and CURES 2.0 database 12 months after the initial surgery (to evaluate for additional opioid prescriptions).

☐ Destroyed once research data is analyzed.

☐ Destroyed after publication/presentation.

☐ Will be maintained; specify time frame and provide the rationale:

☐ Will be stored and maintained in a repository for future research purposes.

☒ Will be retained for six years as this research involves Protected Health Information (PHI) (e.g., IRB documentation, consent/assent forms – NOT the actual PHI).

☐ Will be retained for seven years after all children enrolled in the study reach the age of majority [age 18 in California] as this study includes children.

☐ Will be retained 25 years after study closure as this study involves in vitro fertilization studies or research involving pregnant women.

☐ Will be retained for two years after an approved marketing application, as this is a FDA regulated study. If approval is not received, the research records will be kept for 2 years after the investigation is discontinued and the FDA is notified.

☐ Other:

### D. Photographs, Audio/Video Recordings Retention

1. If subject identifiable audio or video recordings will be collected, specify the timeframe for the transcription and describe retention/destruction plans.

☒ Not applicable: Subject identifiable audio/video recordings will not be collected.

☐ Audio or video recordings transcribed; specify time frame:

☐ Audio or video recordings will be maintained; specify time frame:

☐ Audio or video recordings maintained indefinitely; provide the rationale:

☐ Audio or video recordings destroyed; specify time frame:

2. If subject identifiable photographs will be collected, describe retention/destruction plans.

☒ Not applicable: Subject identifiable photographs will not be collected.

☐ Photographs will be maintained; specify time frame:

☐ Photographs maintained indefinitely; provide the rationale:

☐ Photographs destroyed; specify time frame:

#### **E. Certificate of Confidentiality**

1. Indicate whether a Certificate of Confidentiality (COC) has been or will be requested.

☒ Not applicable: No COC has been requested for this study.

☐ A COC will be or has been requested for this study.

☐ A COC has been obtained for this study. The expiration date of this COC is:

2. Explain in what situations the UCI study team will disclose identifiable private information protected by a COC.

N/A