PROTOCOL TITLE:

Randomized trial on **E**xpectations and **P**ain control **A**dvancement **I**n surge**R**y: **The REPAIR Trial**

PRINCIPAL INVESTIGATOR:

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Version 8

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REGULATORY FRAMEWORK:

Please indicate all that apply:

☐	DOD (Department of Defense)
☐	DOE (Department of Energy)
☐	DOJ (Department of Justice)
☐	ED (Department of Education)
☐	EPA (Environmental Protection Agency)
☐	FDA (Food and Drug Administration)
☐	HHS (Department of Health and Human Services)
☐	VA
☐	Other:

Is this a clinical trial under ICH-GCP E6? ☐ Yes ☒ No

If yes, please confirm that the research team is familiar with and agrees to comply with the investigator requirements cited in ICH-GCP E6. ☐ Yes ☐ No

ICH-GCP E6 can be accessed by copying and pasting this URL into your browser: http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf

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1. Objectives

There are two specific *objectives*. First, assess and incorporate patients' post-operative pain experiences related to pelvic floor surgeries and identify what patients feel is important regarding pain experiences and expectations, their management and pre-operative education. Second, based on patient identified themes, assess the impact of patient-centered pre-operative education on 1) post-operative narcotic use and return to activities and function 2) patient preferences regarding amounts of post-operative narcotics prescribed and 3) to assess the impact on patient satisfaction and preparedness. The *central hypothesis* is that the development of patient-centered, pre-operative education specifically addressing pain issues and narcotic prescribing practices will decrease post-operative narcotic use without curtailing return to normal activity or function. The *rationale* for this hypothesis is that existing evidence-based, post-operative pain guidelines lack requisite patient input and that aligning patient and surgeon goals prior to surgery will help manage post-operative pain expectations, reduce number of opioids prescribed, decrease risk of opioid dependence and improve patient satisfaction and preparedness. Obtaining proof that this approach is clinically feasible and beneficial would positively influence patient care. The central hypothesis will be tested with the following specific aims:

Specific Aim 1. 1a: To identify patient post-operative pain concerns surrounding pelvic floor surgery utilizing qualitative methodology through focus group sessions. 1b: To develop and implement pre-operative patient education based on the domains identified in specific aim 1a. Patient-centered education will address concerns regarding post-operative pain expectations and preferences regarding the amount of opioid prescribed at hospital discharge. *Hypothesis: Patients are concerned and apprehensive about post-operative pain related to surgery. The conceptual themes regarding pain issues can be incorporated into pre-operative patient education, expanding the patient role in decision-making regarding narcotics supplied at hospital discharge.*

Specific Aim 2. 2a: To randomize women undergoing pelvic floor surgery to standard pre-operative education versus patient-centered education (as determined by Aim 1) and evaluate whether patient-centered education, compared to routine education, decreases narcotic consumption without interfering with return to regular activity following hospital discharge. 2b: To test whether patient-centered education decreases the quantity of narcotics prescribed and/or increases patient satisfaction and preparedness. *Hypothesis: Patients exposed to patient-centered pre-operative education that includes pain expectations and patient preference, will decrease quantities of post-operative narcotics consumed and prescribed without interfering with return to activities, improving patient satisfaction and preparedness for surgery.*

Expected outcomes: Investigation of post-operative pain experiences in women who have undergone pelvic floor surgery will allow creation of patient-centered pre-operative educational material and allow inclusion of patients in the shared decision-making process. The resulting *positive impact* will be an improved approach to pre-operative education and management of post-operative pain in women undergoing pelvic floor surgery.

2. Background

Opioid use disorder has reached epidemic proportions in the United States. Opioid prescriptions per capita increased 7% from 2007-2012, with concomitant increases in narcotic associated emergency room visits and opioid-related deaths.[1] A Center for Disease Control (CDC) review reported that long-term opioid use disorder was commonly associated with narcotics prescribed for acute pain and that greater quantities at initial exposure were associated with greater risk of long-term use. Based on these findings, the CDC recommended limiting narcotic use for acute, non-surgical pain to ≤ 3 days.[1]

There is currently no clear consensus regarding how narcotics should be prescribed for pain, including post-operative pain, which has resulted in over 800 pain-management guidelines.[2] Among these are two comprehensive, evidence-based documents cited by the CDC[1] that specifically address post-operative pain management.[3,4] Those guidelines emphasize judicious post-operative narcotic prescribing practices, discouraging opioid misuse while encouraging return to function. The Washington Medical Directors Group[4] provides particularly useful recommendations (Table 1). Perhaps the most important of which are 1) thorough pre-operative counseling, including setting realistic pre-operative expectations regarding post-operative pain and activity, and 2) optimizing non-narcotic analgesics allowing use of the lowest narcotic dose for the shortest duration of time (usually < 14 days).

There has been an absence of significant improvement in opioid prescribing practices despite increased attention to pain addiction issues.[2,5] The large number of proposed guidelines and lack of consensus regarding their use, may contribute to inconsistent implementation of post-operative pain protocols in clinical practice.[6,7] As surgeons, urogynecologists routinely prescribe narcotics for post-operative pain control. Consequently, we can play an important role in curbing the opioid epidemic in the patients we serve.

Urogynecologists lack a standardized approach to post-operative pain management. The ideal method to develop a standardized approach would be to bridge the gap between existing post-operative pain management options using a patient-centered approach. Our overarching goal is to provide pragmatic and replicable methods for post-operative pain management that can be disseminated for use by the urogynecologic community with potential use by the surgical community at large.

3. Study Design

This is a single-site mixed methods (qualitative and quantitative components) comprised of patient focus groups as well as a randomized control trial.

Aim 1 - Substantive data are lacking regarding patient experience and recommendations surrounding post-operative pain. In instances where little literature exists, utilizing qualitative methods can help identify and address patient concerns. We will create a semi-structured interview guide based on existing literature with known and perceived gaps. We will then conduct a minimum of four focus groups, recruiting patients who have undergone pelvic reconstructive surgery in the past 6 months to a year. Given our patient population, we will plan for 2-3 focus groups conducted in English and 1-2 focus groups conducted in Spanish. Based on internal practice data, approximately 15% of our patients

are primarily Spanish speaking. Including Spanish-speaking patients will improve the generalizability of this study since approximately 25% of Spanish-speakers in the US report that they speak minimal to no English.[19] Based on prior experience we will recruit enough women to ensure each focus group has 5-10 participants per session. Our research team is bilingual with vast experience conducting and completing qualitative work.
Qualitative Analysis. According to the principals of grounded theory methodology, focus groups should be iterative, conducting additional sessions until saturation is reached. Saturation is met when no new concepts or themes are identified. Based on these principals and our past qualitative work, we will conduct a minimum of 4 focus group sessions and will continue to conduct sessions until saturation regarding post-operative themes is reached.[20-22] We will audio record each session. The recordings will then be de-identified, transcribed, reviewed, and coded to identify key words and phrases, which will then be grouped to form preliminary themes. Following each focus group session, the transcript will be reviewed and analyzed to identify additional themes and emerging concepts. We will revise the interview guide as needed prior to each successive focus group to ensure that all significant patient themes are identified and explored. Following completion of the sessions, identified themes will be organized into domains and used to create patient-centered education for Aim 2.

Aim 2 - This clinical trial will randomize women undergoing pelvic floor surgery to standardized routine pre-operative education versus standardized patient-centered pre-operative education (as identified in Aim 1) and will compare group differences for the following:
Outcome Measures
Primary Outcome: 1.Opioid Consumption -- Opioid consumption determined by pill counts and translated into Morphine Milligram Equivalents (MMEs), within 2 weeks of hospital discharge. Patients will be required to bring their narcotic medications for pill counts at their routine 2-week follow-up appointment, since this is the most reliable method for checking opioid use. A medication diary will document pattern of opioid and non-narcotic use and may potentially serve as a behavioral modification tool for narcotic consumption.
Important Secondary Outcomes: 1. Opioids prescribed at hospital discharge and *Opioids consumption* at 6-week follow-up. *2. Patient Reported Outcomes Measurement Information Systems (PROMIS)[29] Physical Function SF & Pain Interference Questionnaires* -- at baseline, 2 and 6 week follow-up. These validated questionnaires (available in English and Spanish) measure patient-reported physical activity and pain in the preceding 7 days.[30] Raw scores are translated into standardized scores; mean T-score represents the average score of the general population and a difference of 10 points represents 1 SD away from the mean.
Other Secondary Outcomes: Patient Satisfaction and Preparedness for Surgery: We will administer Global Questionnaires assessing (1) satisfaction with pre-operative education and care and (2) assessing patient's perceptions regarding preparedness for surgery. These will be administered to both Spanish and English speaking patients. Questionnaires will be scored on a 1-5 Likert scale (Strongly disagree to Strongly agree). (Other validated post-operative satisfaction and preparedness questionnaires are not readily available in Spanish; existing Spanish questionnaires are condition-specific -- general or urogynecologic post-operative questionnaires are not currently validated.)

4. Inclusion and Exclusion Criteria

We will recruit women cared for by the University of New Mexico Urogynecology practice at UNMH Women's Care Clinic or Sandoval Regional Medical Center undergoing pelvic floor surgery. Patients who have elected to proceed will be offered study enrollment if they meet the inclusion and do not meet the exclusion criteria.

The *inclusion criteria* are:

1. Subjects are ≥ 18 years of age
2. English or Spanish speaking
3. Patient scheduled for pelvic floor surgery

Exclusion criteria are as follows:

1. Unable to speak English or Spanish
2. Using long acting opioids (e.g. MS Contin, Fentanyl patch)
3. Primary or Pain Healthcare Provider recommends against study participation (eg. If the patient has a history of opioid use disorder or other confounding problems, we will contact the Primary Care Provider or Pain Healthcare Provider for their recommendations regarding study participation)
4. Undergoing surgeries that involve: Neuro/Interstim, Cysto/hyrdro distension, vaginal botox, mesh excision/complications

Special populations such as adults unable to consent, individuals who are not yet adults, pregnant women, and prisoners will not be included in this study.

We will be excluding women who are unable to speak and understand either English or Spanish. The justification for this is the satisfaction surveys are only available in English and Spanish and include the majority of the patients care by our group. Because these are our secondary objectives, it is important to use these standardized surveys. Additionally, we can only conduct focus groups in English or Spanish given our qualitative team is bilingual only in English and Spanish.

5. Number of Subjects

This a qualitative and randomized control trial at a single site – the University of New Mexico's Urogynecology department.

Up to 60 participants will be recruited for the focus groups and up to 198 people will be recruited for the randomized controlled trial at UNM.

Power Calculation & Statistical Analysis:

Based on our prior qualitative experience; approximately 10-12 participants must be recruited to have 6-8 attend the focus group. We plan to conduct 4 focus groups; and need to recruit 48 subjects. Given it is possible thematic saturation will not be achieved after 4 focus groups; we will recruit additional subjects and complete additional focus group until saturation is obtained. Although a few studies describe

opioid prescribing practices following Ob-Gyn surgery, we could not find any studies that reported opioid *consumption* following gynecologic or urogynecologic surgery. In order to perform the power calculations necessary for Specific Aim 2 (comparing opioid use between groups), because the actual number of opioids consumed following urogynecologic surgery is unknown, we will assume that patient-centered pre-operative education will result in a 33% decrease in narcotic consumption following hospital discharge compared to the control group. If we assume that controls consume a mean of fifteen 5 mg oxycodone pills (SD of +/-11 pills), and if we assume that the patient-centered group consumes 33% fewer pills (i.e. 10 pills in the modified education group), we would need a total of 152 participants (76 per group) to complete treatment and follow-up for a two-tailed t-test to have 80% power at α=0.05. Assuming approximately 30% of patients will cancel surgery after randomization (including medical or insurance issues or change their mind) or will be lost to follow-up; we would need to enroll up to 198 women (99 per group) or until our designated power is met. We will perform between group comparisons using Chi-squared tests for categorical variables and t-tests for continuous variables. We anticipate that specific covariates (e.g. baseline questionnaire results, and narcotic use in last 3 months) may be confounders and that multivariable analyses will be required to evaluate the between group differences in outcomes. Note 1: When studies involve consent, an individual is considered a research subject once they have provided consent. If the research includes screening procedures after consent, please indicate the number of subjects that need to be recruited and the number that will actually participate in the research post-screening.

6. Study Timeline

Subjects in Aim 1 will participate in one focus group. Subjects in Aim 2 will participate up to the 6 week post-operative visit. This could occur within a window up of up to 8 weeks past their surgery.
We will be able to complete this project within the planned timeframe outlined below. The UNM Urogynecology Division performed approximately 230 major pelvic floor operations last year (average of 19/month). We will create the database, standardize current pre-operative sessions, and prepare the manual of operations and focus group script for Specific Aim 1 over the next 3 months. We will identify patients for enrollment in the focus groups during this initial period. This preparation will then allow us to successfully execute specific Aim 1 over the subsequent 3 months. We will have biweekly to weekly focus group meetings during the start-up period of the grant cycle. This allows 8-10 weeks to review our findings and develop a patient-centered educational plan. We will then enroll up to 198 women or until our specified power is met over the next 1-4 years given the halt of all elective surgeries with the Covid pandemic(averaging 11 participants/month). We anticipate finishing recruitment by October 2021 and follow up for those randomized by December 2021We, thus, expect to meet our recruitment goals. The last 3 months of the grant cycle will be dedicated to statistical analysis and abstract and manuscript preparation. As all patients receive pre-operative education and have scheduled 2 and 6-week post-operative visits, we anticipate that the vast majority of our patients will be

willing and able to participate in this study. Experience indicates that our patients have willingly participated in previous RCTs with high retention rates. We expect that this pattern will continue. We will continuously evaluate our recruitment numbers.

Timeline	March-May 2018	June-August 2018	Sept 2018-December 2021 (3 years, 3 months)	December 2021-February 2022
IRB submission, Database creation, Focus group recruitment planned, Standardize patient-centered pre-operative education	⟷			
Conduct focus group sessions, Standardize patient-centered pre-operative education		⟷ ⟷		
Recruit & follow 180 patients until 6-weeks after surgery			⟷	
Data analysis, manuscript preparation				⟷

7. Study Endpoints

Investigation of post-operative pain experiences in women who have undergone pelvic floor surgery will allow creation of patient-centered pre-operative educational material and allow inclusion of patients in the shared decision-making process. The resulting positive impact will be an improved approach to pre-operative education and management of post-operative pain in women undergoing pelvic floor surgery.

Primary Outcome: 1.Opioid Consumption -- Opioid consumption determined by pill counts and translated into Morphine Milligram Equivalents (MMEs), within 2 weeks of hospital discharge. Patients will be required to bring their narcotic medications for pill counts at their routine 2-week follow-up appointment, since this is the most reliable method for checking opioid use. A medication diary will document pattern of opioid and non-narcotic use and may potentially serve as a behavioral modification tool for narcotic consumption.

Important Secondary Outcomes: 1. Opioids prescribed at hospital discharge and *Opioids consumption* at 6-week follow-up. *2. Patient Reported Outcomes Measurement Information Systems (PROMIS)[29] Physical Function SF & Pain Interference Questionnaires* – at baseline, 2 and 6 week follow-up. These validated questionnaires (available in English and Spanish) measure patient-reported physical activity and pain in the preceding 7 days.[30] Raw scores are translated into standardized scores; mean T-score represents the average score of the general population and a difference of 10 points represents 1 SD away from the mean.

Other Secondary Outcomes: Patient Satisfaction and Preparedness for Surgery: We will administer Global Questionnaires assessing (1) satisfaction with pre-operative education and care and (2) assessing patient's perceptions regarding preparedness for surgery.

These will be administered to both Spanish and English speaking patients. Questionnaires will be scored on a 1-5 Likert scale (Strongly disagree to Strongly agree). (Other validated post-operative satisfaction and preparedness questionnaires are not readily available in Spanish; existing Spanish questionnaires are condition-specific -- general or urogynecologic post-operative questionnaires are currently unavailable.)

8. Research Setting

The study will be performed at the University of New Mexico (UNMH) Women's Care Clinic and Sandoval Regional Medical Center (SRMC). Potential subjects will be recruited in the UNMH and SRMC clinics. After recruitment, they will undergo the consent process (written or verbally), and fill out initial questionnaires in the outpatient offices, by phone, email link to REDCap or HIPAA compliant zoom, whichever works best for the participant. There are no laboratory tests in this trial other than what would be routinely collected for standard of care. There will be no involvement of any community advisory board. There will not be any research conducted outside of the UNM HSC.

9. Resources Available

The previous PI, Dr. Jeppson joined UNM in 2013 with an impressive pedigree and research experience from his residency at Cleveland Clinic and his FPMRS Fellowship at Brown University in Providence. During his tenure at UNM he has already significantly contributed to the scientific knowledge in our field. As his CV and publication record demonstrate he is clearly committed to an academic research career. He has led and conducted a wide variety of research, including systematic reviews that have fostered changes to medical practice with high quality evidence. He is skilled at leading a research team and is meticulous with deadlines. He is extremely committed and gets things done. This study is a natural extension of his work to improve patient care and clinical outcomes. Dr. Jeppson is an astute, driven, clinical researcher who is already becoming a leader in our field.

Dr. Jeppson's research proposal will pragmatically study and implement an educational intervention to decrease post-operative narcotic use. This research augments his experience and interest in improving clinical care and patient education. Dr. Jeppson's thesis project during fellowship, "Improving patient knowledge about sacral nerve stimulation using a patient based educational video" (published in the Journal of Urology), clearly demonstrates his commitment to patient education. Although that research study evaluated different outcomes, it is similar to this study in that it was a mixed methods project that incorporated patient preferences into educational material.

Dr. Tasha Serna-Gallegos will take over as PI as this was her thesis project as a fellow and Dr. Peter Jeppson has lowered his FTE with UNM as he has moved to a practice out of state.

The University of New Mexico (UNM) urogynecology division operates at two main locations. *UNMH Women's Care Clinic* located in northeast Albuquerque provides a full

range of services for women with pelvic floor disorders. The clinic consists of eight exam rooms and two treatment rooms. Our second location is at *Sandoval Regional Medical Center (SRMC),* a community based facility located in Rio Rancho, New Mexico, a large suburb located outside of Albuquerque.

Research Experience: The Urogynecology Division at UNM has a strong history of conducting high quality research and collaboration with other investigators in the US and abroad and has consistently met or exceeded recruitment goals on time. We were members of the NICHD-sponsored PFDN in the last grant cycle, and have met recruitment goals with high rates of follow-up and accurate data collection.

Our group is well versed in the importance of adherence to protocols, timely completion of regulatory requirements, effective recruitment strategies, and the importance of the inclusion of minority subjects. Research is integral to all aspects of Divisional work; importantly, all members of the clinical team participate in research efforts. There are weekly research meetings to discuss the progress of the ongoing studies within the department, and it is an excellent forum to ensure that all involved are adequately informed of their duties, of the protocol, and of the procedures.

We do not anticipate that emergency care will be needed for this study, however the urogynecology physicians are available on a 24-hour basis, 7 days per week for their patients requiring emergency care.

10. Prior Approvals

There will not be any approvals obtained prior to commencing the research. The study was presented for approval by the Department Chair or Vice Chair of Research. The signed Departmental Review form can be found in the "supporting documents".

This study does not include any ionizing radiation, biologic specimens, or drugs. Medications prescribed to participants will be part of their standard of care.

11. Multi-Site Research

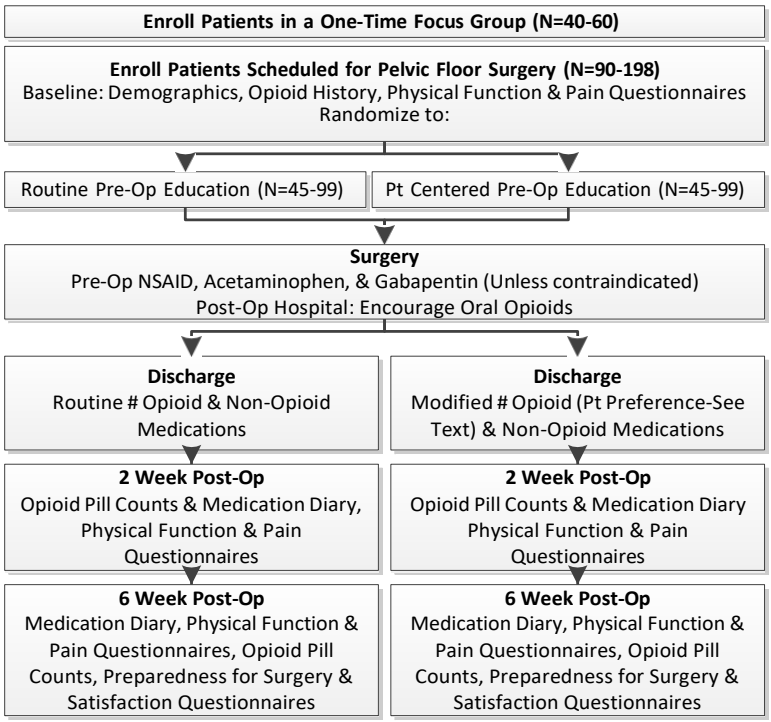
N/A this is not a multi-site study or a FDA regulated trial.

12. Study Procedures

The only procedures subjects will undergo are those that are needed as part of their routine preoperative, intraoperative and postoperative care. There are no procedures related to the study.

All surgeries will take place at UNM Main, OSIS or SRMC operating rooms. Questionnaires and data collection will occur in the Urogynecology clinics at UNM or SRMC, by phone, HIPAA compliant Zoom or email link to REDCap, whichever is best for the participant. All data will be collected prospectively.

Participant Flow through the Study: Figure 1 (N range pending funding)



13. Data Analysis

Power Calculation & Statistical Analysis: Although few studies describe opioid prescribing practices following Ob-Gyn surgery, we could not find any studies that reported opioid *consumption* following gynecologic or urogynecologic surgery. In order to perform the power calculations necessary for Specific Aim 2 (comparing opioid use between groups), because the actual number of opioids consumed following urogynecologic surgery is unknown, we will assume that patient-centered pre-operative education will result in a 33% decrease in narcotic consumption compared to the control group. If we assume that controls consume a mean of fifteen 5 mg oxycodone pills (SD of +/-11 pills), and if we assume that the patient-centered group consumes 33% fewer pills (i.e. 10 pills in the modified education group), we would need a total of 152 participants (76 per group) to complete treatment and follow-up. Assuming approximately 30% of patients will cancel surgery after randomization or will be lost to follow-up; we would need to enroll 198 women (99 per group). We will perform between group comparisons using Chi-squared tests for categorical variables and t-tests for continuous variables. We anticipate that specific covariates (e.g. baseline questionnaire results, and narcotic use in last 3 months) may be confounders and that multivariable analyses will be required to evaluate the between group differences in outcomes.

14. Provisions to Monitor the Data to Ensure the Safety of Subjects

Subjects will participate in focus groups and then receive preoperative education and shared decision making on quantity of opioid prescribed postoperatively. Therefore the risks inherent to participation in the study are only minimal. As this is a minimal risk study, our Data Safety Monitoring Plan will entail the review of data monthly by staff and the PI or a mentoring co-investigator. We will assess for harm such as over treatment

of pain, which is highly unlikely as we are complying with our standard of care. It would be unlikely that the study would require suspension as patients in the intervention arm are actually having less exposure to harm than the standard of care arm. Specific findings we will be looking for are adverse events, serious adverse events and reportable new information.

15. Withdrawal of Subjects

Any participant may withdraw from the study at any time without penalty and will continue to receive the clinical standard of care. A subject may be withdrawn from the study without her consent at the discretion of the physician and study staff if they believe she no longer meets study inclusion criteria or if she meets exclusion criteria, or if they believe that it is not in her best interest to continue study participation. Investigators may withdraw a subject if the subject is not following the study protocol. If a woman is withdrawn from the study either at her own discretion or that of the research staff, she may continue with the planned surgical procedure performed in the usual fashion.

To minimize withdrawal from the study, patients will be randomized at their pre-operative visit. According to the 2010 CONSORT guidelines, we will analyze all participants assessed for eligibility within the study. We will document reasons for withdrawal from the study including failure to meet eligibility criteria or participant declining enrollment into the study. We will report eligibility criteria not met or reasons for declining participation in the study. The withdrawal procedure is clearly documented in the study consent.

16. Data Management/Confidentiality

Randomization assignment will be generated by a computer based randomization table and assigned by a research coordinator. Assignments will be kept in sealed opaque envelopes numbered sequentially, and on the day of the patient's pre-operative visit, the surgeon will call a research coordinator who will open the next envelope in the sequence. All data collection sheets and questionnaires will contain the subject number and day of the clinic visit or day of completion. No other patient identifiers will be collected. PHI including patient name, date of birth, phone number, and medical record number will need to be collected to track for appointments.

The data collection, HIPAA and consent forms will be maintained in a locked file cabinet in the OBGYN administrative area. A separate folder will be designated for each participant. The offices have the additional security of being badge-access only for OBGYN department employees. A key matching study number to subject's name will be in a spreadsheet secured on a password protected computer.

The only PHI collected will be patient name, date of birth, medical record number and telephone number for site use only and to ensure patient follow up. This will not be entered into the database, but it will be kept with the other identifying information.

The data does not include sensitive information or information requiring additional protection.

Electronic data entry will be performed in the OBGYN administrative offices, using the de-identified subject study number. The electronic data will be encrypted, password protected, and stored on the secure UNM OBGYN department server. This server's electronic security is monitored / maintained by the Health Sciences Library and Informatics Center (HSLIC). A REDCap database will be created to collect, store and manage the data. REDCap databases are reposed securely. The REDCap database is only accessible using a individual unique login and password and access is only provided to co-investigators. Access is restricted to co-investigators and will be protected using the unique REDCap login and password provided to each co-investigator.

Access to the files and REDCap will be restricted to research personnel and Investigators and will be locked or protected using the unique REDCap login and password provided to each co-investigator. The data will be stored for 5 years after completion of analysis and then will be destroyed.

A Certificate of Confidentiality will not be used to protect data from forced release. No data will be transported to outside locations or shared with external institutions. Focus groups will be audio-recorded; the transcriptions will be de-identified and the original audio-recordings will be destroyed following manuscript publication. There will be no video recordings or photographs taken.

17. Data and Specimen Banking

As stated above, the data collection, HIPAA and consent forms will be maintained in a locked file cabinet in the OBGYN administrative area. A separate folder will be designated for each participant. A key matching study number to subject's name will be stored on a password protected computer on a secure UNM OBGYN department server. In order to further ensure patient confidentiality, the identifying information will be kept separately from the numbered study files in a locked cabinet. The data will be maintained for 5 years after completion of the study and then destroyed.

No specimens will be archived for future use. Additionally, this is neither a multi-center study nor will any information be banked or archived elsewhere.

18. Risks to Subjects

Focus groups by their nature cannot be anonymous. However, participants will be asked to keep what was discussed in the focus groups confidential and will be asked to use their first names only. The focus group transcripts will be de-identified. Risks of enrollment in the study include the risk of breach of confidentiality. We will take every measure to try to ensure the security and confidentiality of participants. This may result in stigmatization or hardship. Participants will be recruited in a private room and will have ample time to consider whether they want to participate in the study. Also, locked filing cabinets will be used to protect patient consent information and collected data. The link identifying patients and their study numbers will be also be stored on a password protected computer on a secure UNM OBGYN department server. There are risks of stress, emotional distress, and inconvenience.

Pregnant women will not be included in the study, so there is no risk to embryos/fetuses.

19. Potential Benefits to Subjects

Participation in this study may provide information that may help other people who have a similar medical problem in the future.

20. Recruitment Methods

We will recruit women from our urogynecology clinical practice at UNM and SRMC.

The urogynecology clinics at UNM and SRMC have a large referral population of patients who undergo pelvic floor surgery. Participants will be identified in the clinics at UNM/HSC and Sandoval Regional Medical Center by investigators. All patients scheduled for surgery will be approached for recruitment for the RCT portion of this study. The focus group participants will be identified through previous study consents that said they would be willing to be contacted for future research. Additionally, the urogynecolgy division keeps a computer record of the patients that had urogynecologic surgery over the past year as part of our standard care and scheduling. These patients may also be contacted by their surgeon to see if they are interested in participating in a focus group. Subjects are encouraged to consult with family, friends, and primary health care providers, as well as communicate any questions they may have before beginning the consent process.

If a woman is withdrawn from the study either by her desire or that of the research staff, or does not desire to participate, she will be offered the same treatment options.

There will be no other additional materials to recruit subjects.

21. Provisions to Protect the Privacy Interests of Subjects

Focus groups by their nature cannot be anonymous. However, participants will be asked to keep what was discussed in the focus groups confidential and will be asked to use their first names only. The focus group transcripts will be de-identified.

Privacy concerns are taken into account with every patient seen at the UNM and SRMC. Participants approached and/or interviewed in the clinic setting will be in private offices or examination rooms in the UNM or SRMC clinic, where all staff, including research staff, are well-versed in sensitive health care discussions and procedures. Telephone interviews for recruitment and study data gathering are conducted in the research staff area or private physician offices, where all staff have received CITI Training. The office area designated for the entire urogynecology research staff is isolated from the clinical administrative staff area, providing protection for participants and potential participants during screening, recruitment, study-designated calls, and data entry.

All study sheets used to collect patient information will be de-identified.

At all times throughout the clinical investigation confidentiality will be observed by all parties involved. All data will be secured against unauthorized access. Privacy and confidentiality of information about each subject will be preserved in study reports and in any publication. Each subject participating in this study will be assigned a unique identifier. HIPAA authorization is within the consent. All documents containing personal health information (screening logs, consent documents, data forms) are maintained in locked file cabinets with access available only to research staff and investigators. Data is entered into a password-protected system. No individual identifiers are entered into the system. The sole link with personal information is maintained by the research team on a password protected computer on a secure UNM OBGYN department server with access limited to authorized research staff and investigators. This information is only to be used at the study center.

22. Economic Burden to Subjects

Research Procedures	Number of Samples/Procedures	Responsible Party	
		Study	3rd Party Payer or Participant
Focus Group – Aim 1	1	☒	☐
Demographic Form	1	☒	☐
PROMIS Physical Function SF	3	☒	☐
PROMIS Pain Interference SF	3	☒	☐
Patient Satisfaction and Preparedness for Surgery Questionnaire	1	☒	☐
Medication Diaries	2	☒	☐
Opioid History	1	☒	☐
_____	_____	☐	☐
Standard of Care Procedures	**Number of Samples/Procedures**	**Responsible Party**	
		Study	**3rd Party Payer or Participant**
Urogynecology Clinic Visits pre-op, 2 & 6 week post-op	3	☐	☒
Pelvic Floor Surgery	1	☐	☒
Pain medication post-op	Varies per patient	☐	☒
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐
_____	_____	☐	☐

23. Compensation

Pending funding - For enrollment in Aim 1, participants will receive a $50 merchandise card for their participation in one focus group. For enrollment in Aim 2, participants will receive a $10 at their initial visit, $20 at their 2-week post-operative visit and $20 at their 6-week post-operative visit for a total of $50 in merchandise cards for their participation in the study. This incentive will offset the cost of subject's time and transportation while participating in the study.

24. Compensation for Research-Related Injury

If participants are injured or become sick as a result of this study, UNM HSC or SRMC will provide emergency treatment at the study participant's cost. No commitment is made by the University of New Mexico Health Sciences Center to provide free medical care or money for injuries to participants of the study. Reimbursement for treatment for all related costs of care will be sought from the participant insurer, managed care plan, or other benefits program. The participant will be responsible for any associated co-payments or deductibles required by the insurance. Participants will be asked to report any illness or injury they believe to be related to the study to the investigator or research staff. Participants will be given telephone contact information for the urogynecology office for the purpose of asking any questions or stating any concerns about the study or treatment as a research subject. They may also be directed toward the HRPO. This language will be stated in the consent document and reviewed during the informed consent process. There is no additional risk to participate in this study.

25. Consent Process

Patients will be approached about the research study at the urogynecology clinics at UNM and SRMC, as well as on phone and by HIPAA compliant Zoom, after the patient has decided to have surgery. The study consent will be obtained by one of the research team members. Verbal consent will be noted on the updated consent form with a space to also sign if the patient has an office visit in person. Due to the pandemic, research coordinators are mainly working from home and going through the consent with participants by phone for the safety of everyone. Privacy is still maintained as the coordinator ensures they have a place they can talk privately by phone. Additionally, care will not be withheld if they decide not to participate.

They will have multiple opportunities to ask any questions that they may have, and they will also be provided with the clinic's contact information to get in touch with research investigators to address any additional questions or concerns.

Subjects will be reassured that participation is completely voluntary and does not affect their treatment, their relationship with their providers, or the university to minimize the possibility of coercion or undue influence. The patients will be asked that they understand the opportunity to participate and their complete freedom to decline. This will also be asked if they understand and if they have any questions. There is no minimum time period needed between informing the patient of the study and time of consent. Subject will be encouraged to take as much time as they need.

This study will obtain HIPAA authorization prior to enrollment. HIPAA authorization is embedded within the study consent form, which will be reviewed with all participants by the physician or research coordinator obtaining consent. Specific information that will be obtained includes prior medical history, surgical history, reproductive health history including child bearing, drug allergies, age, and ethnicity. This information will be obtained by health care providers, not research coordinators, as deemed necessary for a

more complete and accurate medical history of the patient and is part of the standard of care during preoperative assessment.

Spanish speaking patients will be included. We will submit the translated documents once the study is approved by the IRB.

Cognitively Impaired Adults will not be included in the study.

All subjects will be 18 years of age or older. No infants, children or teenagers will be enrolled in the study.

26. Documentation of Consent

We plan to document consent, and the Consent form is attached. We do not plan on collecting/storing tissue samples. We will have the option to consent verbally. We will not be using a script, information sheet, or other mechanism.

27. Study Test Results/Incidental Findings

We do not intend to share study test or procedure results with study participants. Additionally, we do not anticipate that the research being conducted will result in incidental findings. Every patient will receive the practice's standard of care regarding a pre-operative work up, which may include different laboratory tests and imaging studies, as determined by their other active medical issues. These results are not part of the research being conducted and will hence be disclosed to the patient as appropriate for standard of care.

28. Sharing Study Progress or Results with Subjects

The patients will not be masked to their study arm. We do not intend to seek out study participants to disseminate information once the study is complete. Women who are interested in the results will be provided the information where to read the manuscript once it is published. Study results for individual participants will not be shared.

29. Inclusion of Vulnerable Populations

There will not be any vulnerable populations included in this study. Those electing for surgery will not be coerced into doing so, nor will they be coerced into participating in this trial.

30. Community-Based Participatory Research

NA. There will be no involvement of the community in this research.

31. Research Involving American Indian/Native Populations

NA. This research does not specifically target this population. If a Native American woman is a candidate for this study, she will be offered participation.

32. Transnational Research

NA. This study is not transnational.

33. Drugs or Devices

NA. This research does not involve drugs or devices.

Checklist Section

This section contains checklists to provide information on a variety of topics that require special determinations by the IRB. Please complete all checklists relevant to your research.

I. Waivers or Alterations of Consent, Assent, and HIPAA Authorization

A. Partial Waiver of Consent for Screening/Recruitment

We are not requesting a partial waiver of consent

Partial Waiver of HIPAA Authorization for Screening/Recruitment

We are requesting a partial waiver of HIPAA authorization to prescreen participants. Investigators will review the medical records of potential participants in PowerChart to determine if they are a good candidate for participation. They may review information such as medical history including surgeries and medications.

The protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information for which an authorization or opportunity to agree or object is not required by 45 CFR 164.512.

We will be using PowerChart to screen potential participants who have already had surgery at UNMH or SRMC. We will review their medical records through PowerChart to ensure they meet the inclusion/exclusion criteria. PHI that will be reviewed in PowerChart will include information such as date of birth, gender identity, and diagnoses. The only PHI that will be stored will be the patient's name, MRN, and the reason they were not approached or included in the study. This spreadsheet is an encrypted document and will be destroyed at the conclusion of the study.

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