UC Riverside
RESEARCH INFORMED CONSENT

Title of research study: Lights, Camera, Action: Evaluating the Impact of Randomized Preoperative Instructional Video on Patient Preparedness following Minimally Invasive Gynecologic Surgery

Investigators:	Janet Cruz, MD Samar Nahas, MD, MPH

This section provides highlights of this research study to help you decide whether or not you should participate. Carefully consider this information and the more detailed information provided below the section. Please ask questions about any of the information you do not understand before you decide whether to participate.

- **Purpose**: This is a research study that will evaluate the impact of a preoperative video for patients undergoing a minimally invasive gynecologic surgery. The video will prepare patients to understand what to expect and how to take care of themselves after the procedure. The effectiveness of the video will be evaluated via a questionnaire to see if patient's who watched the video had better recovery outcomes, greater understanding, and less anxiety when compared to the group of patients who did not watch the preoperative video.
- **Procedures:** Participation in this study will involve a preoperative appointment where you will be given *either an unlimited amount of views to the video or you will be provided oral instructions regarding your upcoming surgery. During your postoperative appointment a survey will be given to see your overall satisfaction with preoperative counseling.* It is expected that your participation will last *1 month.*
- **Risks:** Risks of this study are minimal Some of the foreseeable risks or discomforts of your participation include *if questions should arise from the video or during your preoperative counseling, you can always message the surgeon prior to surgery. If your questions have not been fully answered then another preoperative visit could be scheduled, however this could delay your surgery.*
- **Benefits:** You may not benefit from this research.
- **Alternatives:** Instead of being in this research study, your choices may include, *not being included in the study and thus receiving instructions as you would be depending on the surgery being provided.* Your alternative to participating in this research study is to not participate.
- **Compensation:** You will not be paid for your participation.
- **Voluntary Participation:** Your participation in this study is voluntary. You can decide to participate or not to participate, or to withdraw from it at any point without penalty or loss of benefits to which you are otherwise entitled to or already have.

The remainder of this form contains a more complete description of this study.

Purpose

You are being asked to participate in a research study. This is a research study about evaluating the impact of a preoperative video for patients undergoing a minimally invasive gynecologic surgery. The video will prepare patients to understand what to expect and how to take care of themselves after the procedure. The effectiveness of the video will be evaluated via a questionnaire to see if patient's who watched the video had better recovery outcomes, greater understanding, and less anxiety when compared to the group of patients who did not watch the preoperative video.

Study researchers, Janet Cruz MD, Samar Nahas MD, Nayo Macauley, MS, Mallory Stuparich MD from the UCR Department of *Obstetrics and Gynecology* will explain this study to you.

You are being asked to take part in this study because you are being scheduled for minimally invasive gynecologic surgery.

Am I Eligible To Participate in This Study?

You must meet the following requirements to be in the study:

Inclusion Criteria:

- You must be female.
- You must be between the ages 18 – 65 years old.
- Your surgeon must be part of UCR Health Gynecology physician.
- You must be undergoing Laparoscopic/robotic surgery.
- You anticipate same day discharge from your surgery
- You must be able read English

Exclusion

You cannot participate in this study if you:

- You have receiving postoperative chemotherapy in the 6-week postoperative period
- You are under the age of 18
- You have plan on having an open Laparotomy surgery
- You are pregnant or planning on coming pregnant

Investigator Financial Conflict of Interest

No one on the study team has a disclosable financial interest related to this research project.

What happens if I say yes, I want to be in this research?

If you decide to participate in this research study, the next steps will be:

- *During your preoperative visit you will receive instructions regarding your upcoming surgery.*

- *Your instructions will be provided by either a 10 ten- minute video that you can watch at any time prior to surgery, as many times as you would like, **or** they will be provided by your surgeon without a video.*

- *The preoperative visit will be completed by your surgeon and will take approximately 30 minutes.*

- *The preoperative visit is either in person in our office or via tele-health mychart visit.*

- *Afterward, during your postoperative visit you will be given a questionnaire to complete concerning your pre-operative counseling experience. It should take about 10 minutes to complete this questionnaire.*

  Other information will be gathered from your medical records, including age, ethnicity, BMI, smoking status, narcotic use before surgery, pain levels before surgery, preoperative hemoglobin, indication for surgery, surgical procedure, diagnosis, presence of other pain disorders such as interstitial cystitis, fibromyalgia, intraoperative complications, and intraoperative blood loss

- *The research will not include whole genome DNA or RNA sequencing.*

Study location(s): All these procedures will be done at UCR Women's Health Office at 19330 Jesse Lane, Riverside CA 92506

Is there any way being in this study could be bad for me?

We do not anticipate any foreseeable risks or discomforts to you participating in this study other than those encountered in day-to-day life.

Participating in this research study may involve risks or discomforts that include:

- *Feeling uneasy or anxiety surrounding your upcoming surgery.*
- *Having more questions regarding your upcoming surgery.*

- **Randomization risks:** You will be assigned to a study group by chance (like a coin flip) rather than by any medical decision by the researchers. You will be randomized to watch a pre-operative video, while others will receive standard pre-operative counseling.
- **Unknown Risks:** There are no unknown risk associated with this study.
- For more information about risks and side effects, ask the Janet Cruz, MD or Samar Nahas MD, MPH.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include having all questions regarding your upcoming surgery answered, feeling prepared and confident regarding postoperative care and recovery.

What happens to the information collected for the research?

Information collected for this research will be maintained securely and de-identified. The data will be maintained until the conclusion of the study, which will be approximately 1 year to complete. The data will be compiled and analyzed and written in article form for submission to a publication journal.

Will information about me be kept private?

We will do our best to make sure that the personal information gathered for this study is kept private. However, we cannot promise complete confidentiality and if required by the law, your personal information may be disclosed. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Authorized representatives from the following organizations may review your research data for the purpose of monitoring or managing the conduct of this study:

- The Institutional Review Board (IRB) that reviewed this research

If you do not have a UCR EPIC medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCR EPIC medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record.

After identifiers have been removed, your data may be used for future research without additional consent.

Can I be removed from the study without my OK?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include if postoperative survey was not completed. The researcher will notify you if this occurs.

Can I stop being in the study at any time?

You can stop taking part in the study at any time. If you would like to stop, please contact the PI Janet Cruz or Samar Nahas by emailing *janetcr@medsch.ucr.edu or anyone from the research team*. If you choose to withdraw from the study, your data will be deleted if still identifiable; however, if your data has already been de-identified, it will not be able to be removed from the study.

Will I receive payment for being in this study?

You will **not be** compensated for taking part in this study.

The results of this study may have commercial value to the sponsors, UC Riverside, and/or the researchers. Please know you will have no legal or financial interest in any commercial development resulting from the research or from the information or materials collected.

Are there alternatives to being in this study?

An alternative to being in this study is to not participate.

Will I receive results from this research?

Clinically relevant research results, including individual research results, will be expected to be published in a journal, where results could be easily found by participants, but no individual participation will be identified in the publication as all participants will be de-identified.

If you are interested in receiving the overall research results following completion of the study, please contact the researcher via *janetcr@medsch.ucr.edu*

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at janetcr@medsch.ucr.edu *or anyone on the research team listed on this form*

If you have questions about your rights or complaints as a research subject, please contact the UCR IRB Chairperson at (951) 827 - 4802 during business hours, or to contact them by email at irb@ucr.edu.

CONSENT

You have been given a copy of this consent form to keep.

Participation in research is voluntary. The decision to participate, or not participate, is solely up to you. You have the right to decline to be in this study, or to withdraw from it at any point, without penalty or loss of benefits to which you are otherwise entitled to or already have.

If you wish to participate in this study, you should sign below.

You will also be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

_____	_____
Date	Participant's Name (Print)
	_____
	Participant's Signature for Consent