**The Cleveland Clinic Foundation**
**Consent to Participate in a Research Study**

**Study title:** Are Virtual Visits for Delivery of Postoperative Care Following Urogynecologic Surgery Equal to Office Visits? The VIDEO Randomized Trial
**Sponsor:** N/A
**Principal Investigator:** Cecile Ferrando, M.D. M.P.H., Phone (216) 444-0642
**After hours phone contact** #: (216) 444-2200. Ask the operator to page the 'GYN on call.'

## KEY INFORMATION

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

### What should I know about a research study?

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

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

We invite you to take part in a research study because you are scheduled for surgery. The purpose of this study is to learn if patients are equally satisfied with seeing their surgeon after surgery through a video visit compared to an in-person visit.

You will be asked to complete one brief questionnaire before your surgery. When you follow up with your surgeon at 6 weeks after your surgery, you will be asked to complete two brief questionnaires relating to your satisfaction with your postoperative visit. Your participation in this research study will last about 6 weeks and will conclude after your scheduled six-week postoperative visit. We will collect information from the medical record up to 12 weeks after your surgery.

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

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

The main risks associated with this study are those related to the potential inconvenience you may experience should there be any technological issues during your visit. Our team of providers will try to ensure that your postoperative visit goes smoothly. Another risk of participating in this study is related to your privacy; however, many measures are taken to ensure that your privacy is maintained.

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

**Why might you choose to volunteer for this study?**

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

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

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

Taking part in this study is voluntary. The alternative to being in this study is to not participate.

More detailed information about the alternatives to this study can be found in the section labeled "Alternatives."

## DETAILED INFORMATION

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

## 1. INFORMATION ON THE RESEARCH

**Why is the research study being done?**

Postoperative visits have traditionally been conducted as in-person office visits. In the recent years, there has been a rapid increase in the use of telehealth in different areas of healthcare. However, there are no studies specifically looking at the use of video visits for follow-up in women who are undergoing the type of surgery you are scheduled to have, and comparing whether or not they are equal to in-person visits.

The purpose of this study is to learn if virtual visits through videoconference are similar to in-person visits in terms of patient satisfaction and safety profile and can be offered as an alternative option to patients for their postoperative follow-up appointment with their surgeon. The safety profile is based on adverse events or unexpected medical problems that occur during the study period.

**How Many People Will Take Part in this Study?**

Approximately 100 people will take part in this study at Cleveland Clinic.

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

On the day of your preoperative visit, you will be randomized (like the flip of a coin) to one of two groups. Neither your doctor nor you can choose which group you are in. It will be chosen by chance. One group of patients will see their surgeon/provider in-person in the office at approximately 6 weeks after their surgery. Another group of patients will see their surgeon/provider virtually through videoconferencing at approximately 6 weeks after their surgery.

You will be asked to complete one brief questionnaire before your surgery. After your surgery, you will follow-up with your surgeon/provider at 6 weeks either in-person or virtually, and you will be asked to complete two brief questionnaires relating to your satisfaction with your postoperative visit. All questionnaires can be completed electronically or with paper forms, depending on your preference. Each questionnaire will take 5 minutes to complete.

Your participation in the research study will last about 6 weeks, starting at your preoperative visit and concluding after your scheduled postoperative visit at six weeks. Study information will be collected from the medical record, direct contact, and questionnaire responses. We will collect information from the medical record up to 12 weeks after your surgery.

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

**TEXT MESSAGING USE RELATED TO THE RESEARCH**

By initialing below to "Opt in", you give permission for us to text periodic reminders to complete the study questionnaires. If you do not agree to allow us to use text messaging for this reason, your study status will not be affected. Please initial below if you agree (Opt in) or if you disagree (Opt out).

Initial one:

Opt in: _____ Participant Initials

Opt out: _____ Participant Initials

## 2. ALTERNATIVES

### What are the alternatives to participation in the research study?

Taking part in this study is voluntary. The alternative to being in this study is to not participate and to follow-up with your surgeon after your surgery either in-person or virtually, based on your preference.

## 3. RISKS

### What are the risks of participating in the research study?

The main risks associated with this study are those related to the potential inconvenience you may experience should there be any technological issues during your visit. Our team of providers will try to ensure that your postoperative visit goes smoothly. If your visit cannot be completed due to technological issues, we will make sure to reschedule your follow-up appointment at another time that is convenient for you.

### Confidentiality Risks

There is a potential risk of loss of confidentiality of your data. Every effort will be made to keep your information confidential. The principal investigator will do their best to protect your privacy, including your personal identity and all personal medical information. You will be identified not by your name, but by an identification code (identification number). We will store all data in a password protected database (REDCap) with unique identifiers that will protect patient confidentiality. Only the study investigator and coordinators will have access to the data collected, which is protected for your confidentiality. This is further discussed below in the section entitled “Privacy and Confidentiality”.

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

### Questionnaire/Survey Research

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

## 4. BENEFITS

### What are possible benefits of participating in the research?

There is no guarantee that you will personally benefit by participating in this research study. However, taking part in this study may help us to better understand how we can improve patient satisfaction after surgery and help patients undergoing surgery like yours receive better postoperative care in the future.

## 5. COSTS

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

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

## 6. PAYMENT

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

Yes. You will receive a total of $50 in the form of a check in the mail from Cleveland Clinic for your participation in this study. The payment will be prorated according to completion of individual questionnaires. Check payments will be sent via postal mail and will take between 3-4 weeks to process and issue.

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|---|---|
| Preoperative Questionnaire | $10 |
| Postoperative Questionnaire #1 | $20 |
| Postoperative Questionnaire #2 | $20 |
| TOTAL | $50 |

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

## 7. RESEARCH RELATED INJURY

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

In the event you suffer a research related injury as a result of being in this study, Cleveland Clinic will provide appropriate medical treatment for such injury in a timely manner. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of Cleveland Clinic or any of the physicians or other personnel involved in the study. If you believe that you have been injured as a result of participating in the study, please immediately contact your Cleveland Clinic study doctor even if you may have already been seen or treated by another doctor. If you are seen or treated by a doctor other than the study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you as it may help such doctor treat you.

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

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

## 8. PRIVACY AND CONFIDENTIALITY

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

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

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

## Authorization to Use/Disclose Protected Health Information

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

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

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

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

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

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

## Clinical Trials Language

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search the Website at any time.

## 9. QUESTIONS

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

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

## 10. VOLUNTARY PARTICIPATION

### What are your rights as a research participant?

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

## 11. SIGNATURES

### Statement of Participant

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

_____
Printed name of Participant

_____ _____
Participant Signature Date

### Statement of Person Conducting Informed Consent Discussion

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

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date