# *ASSESSMENT OF VIDEO-CONFERENCE TECHNOLOGY FOR POST-OPERATIVE FOLLOW UP IN A UROGYNECOLOGIC POPULATION*

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# UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT COMBINED INFORMED CONSENT HIPAA AUTHORIZATION FORM

**Protocol Title:** Assessment of video-conference technology for post-operative follow up in a urogynecologic population

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## Why am I being asked to volunteer?

You are being invited to participate in a research study because you are seeking medical care with an urogynecologist and we would like to learn if mobile video-conference technology can be utilized to conduct routine post-operative virtual clinical encounters (VCE). Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the investigator and/or the research team about this form. If you decide to participate, you will be asked to sign this form. Your doctor may be an investigator in this research study. As an investigator, your doctor is interested both in your clinical welfare and in the conduct of this study. Before entering this



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study or at any time during the research, you may want to ask for a second opinion about your care from another doctor who is not an investigator in this study. You do not have to participate in any research study offered by your doctor.

## What is the purpose of this research study?

Patients who undergo pelvic reconstructive surgery (that is, surgery for pelvic organ prolapse, incontinence or both) will require routine post-operative follow up visits with their surgeons and surgical team. You typically will have your first post-operative follow up visit around 30 days after surgery and your second post-operative follow up visit around 90 days after surgery.

This study is aimed to assess if mobile video-conference technology can be utilized to conduct virtual clinical encounters to replace some of your in-office post-operative visits. We are interested in determining if our patients are easily able to participate in these virtual encounters and to assess their attitudes regarding these visits. We would also like to determine if there are any cost savings to the patients with this new technology. The ultimate goal is to help our office and office staff develop new and meaningful strategies to improve communication with our patients and expand access to care.

## How long will I be in the study?

Your participation will start at the time of consent and end once you complete your second post-operative visit (typically around 90 days after your surgery). We expect to complete the analysis of the study within 6 months after all participants have completed the study.

## What am I being asked to do?

If you choose to participate in the study, you will be randomized to either traditional post-operative follow up or virtual clinical encounters via video-conference technology.

In the traditional follow up you will receive a telephone call from your surgeon's nurse about 48-72 hours after being discharged home from the hospital following your surgery. You will come into the office for two post-operative appointments with your surgeon, the first will occur around 30 days after surgery and the second will occur around 90 days after surgery. After the first clinical visit you will complete a telephone survey administered by a member of the research staff. After you second clinical visit you will be asked to fill out a survey at the end of your visit.



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For the virtual clinical encounters, you will receive a video-conference call from your surgeon's nurse about 48-72 hours after being discharged home from the hospital following your surgery. Your first post-operative follow up will be a virtual clinical encounter with your surgeon about 30 days after your surgery. The second post-operative follow up will be an in-office visit with your surgeon about 90 days after your surgery. After your 30-day virtual clinical encounter you will complete a telephone survey administered by a member of the research staff. After your 90-day in-office visit you will be asked to fill out a survey at the end of your visit.

You will be randomly assigned to one of these groups at the time of this consent. The two post-postoperative follow up appointments are routine and would occur even if you do not participate in this study.

The survey will consist of questions related to your experiences with either the traditional follow up or the virtual clinical encounters. The surveys will also ask you questions regarding travel, lost time and costs related to your appointments. The surveys should take no more than 15 minutes to complete after each session. The survey results will be tabulated at the end of the study to compare the traditional follow up with the virtual clinical encounters. The answers to survey questions will have no bearing on your medical care.

## What are the possible risks or discomforts?

There is a potential loss of confidentiality; that is, someone could find out that you have participated in this study, and potentially any data on you that has been collected during the study. This could potentially lead to embarrassment and loss of personal health information. However, we will decrease this risk through the following: all data needed for the study will be stripped of any identifiers (such as name and medical record number) and associated with an assigned subject identification number only, so that it cannot be directly linked to you. Also, all files, forms, and any consent forms or any other documents that could link to you will be locked in a secure area at all times. Only investigators involved in this study will have access to these files.

Additionally, the virtual clinical encounters occur via Vidyo. Vidyo is a HIPAA compliant encrypted video-conferencing service. This technology has been embedded directly into our electronic medical record system to allow for additional security behind the firewall of the University of Pennsylvania Health System. All virtual clinical encounters are live and there is no capability to records any of these encounters, therefore they do not get saved on any servers. These encounters with your healthcare providers occur in a private

rooms in the clinical areas of the office. You will only be interacting with members of your healthcare team during the virtual clinical encounters.

If at any time during the virtual clinical encounter, the health care provider feels that you should be seen in the office or the emergency room, they will advise you of this and facilitate making an office appointment for you or by directing you to an emergency room.

## What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

## What are the possible benefits of the study?

The study may benefit you by decreasing the number of times you physically need to present to the office after your surgery. This can lead to time and cost savings without altering any of your post-operative outcomes. However, you may not get any benefit from being in this research study.

Additionally, this study may benefit society and future patients by providing an alternative method of communication with healthcare providers in the postoperative period.

## What other choices do I have if I do not participate?

Participation is completely voluntary. Choosing not to participate will have no bearings on your medical care. If you do not participate, you will continue the standard of care with two in-office post-operative follow up visits. If you are randomized to virtual clinical encounter, you may choose at any time to stop participating and we will make you an appointment to come into the office for a traditional post-operative office visit.

## Will I be paid for being in this study?

There is no compensation for participation in this study.

## Will I have to pay for anything?

No. The virtual clinical encounters will not cost anything to you. They will occur through a free software application that you will download to your smartphone



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or tablet. You can connect to the virtual clinical encounters with Wi-Fi or a smartphone data plan.

"You are still responsible for any deductibles or applicable co-pays for routine office visits, scans and blood work. Please talk to your doctor and study team about putting you in touch with a financial counselor to determine exactly what the deductible and co-pay will be for you; this is highly variable depending on your type of insurance.

## What happens if I am injured from being in the study?

There is a very low risk of incurring any injury from being in the study. If you have any medical concerns during your virtual clinical encounter or at any time during your post-operative period we will bring you into the office for an in person visit or direct you to the emergency room.

However, if any injury were to occur, we will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed on page one of this consent form.

## When is the Study over? Can I leave the Study before it ends?

Your participation in the study ends after you have completed the survey at the end of your second post-operative follow-up visit (in-office visit for all patients). You may leave the study at any time by informing your healthcare provider of your decision. The overall study is expected to end after all participants have completed their surveys and all information has been collected.

This study may also be stopped at any time by your physician or the study Sponsor without your consent because:

- The Primary Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.



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- The Sponsor or the study Principal Investigator has decided to stop the study.

If you decide to participate, you are free to leave the study at anytime. Withdrawal will not interfere with your future care.

## Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

Each participant will be given a unique identification number that is not related to your medical record number. All documents related to your participation will only carry your participant identification number and be de-identified of any personal health information. All documents, including surveys and data collection forms, will be stored in a secured location accessible only to the Principle Investigator of the study.

## *Electronic Medical Records and Research Results*

## What is an Electronic Medical Record and/or a Clinical Trial Management System?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

Information related to your participation in clinical research will also be contained in the CTMS.

## Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

## What information about me may be collected, used or shared with others?

The following information will be collected and used in the study:

- Date of birth
- Telephone number
- Information regarding your surgery and any post-operative complications
- Your survey answers

## Why is my information being used?

Your information is used by the research team to contact you during the study. Your information is used to:

- Do the research
- Oversee the research
- To see if the research was done right.

## Who may use and share information about me?

The following individuals may use or share your information for this research study:

- Dr. Daniel Lee (the principal investigator of the study and fellow Urogynecologist)
- Dr. Lily A. Arya (attending Urogynecologist)
- Dr. Heidi Harvie (attending Urogynecologist)
- Dr. Pamela Levin (attending Urogynecologist)
- Dr. Uduak Andy (attending Urogynecologist)

## Who, outside of the School of Medicine, might receive my information?

- An appointed statistician to analyze data at completion of the study



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Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

## How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire. Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission
- As permitted by law

## Can I change my mind about giving permission for use of my information?

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

## What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.



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When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

| Name of Subject (Please Print) | Signature of Subject | Date |
|---|---|---|

| Name of Person Obtaining Consent (Please Print) | Signature | Date |
|---|---|---|



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