CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE: A Standardized Patient Education Video Program for Improvement of Post-Operative Recovery after Outpatient Upper Extremity Surgery

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This consent form contains important information to help you decide whether to take part in a research study. The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends. Please keep in mind:

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- **Why this research study is being done;**
- **What will happen during the study;**
- **Any possible benefits to you;**
- **The possible risks to you;**
- **Other options you could choose instead of being in this study;**
- **How your personal health information will be treated during the study and after the study is over;**
- **Whether being in this study could involve any cost to you; and**
- **What to do if you have problems during the study or questions about this study.**

<u>Please read this consent form carefully.</u>

WHAT IS INFORMED CONSENT?

You are being asked to take part in a research study that will study the effect of an education program on recovery after surgery, including your understanding of wound care, your assessment of your pain levels, and your need for pain medication. The research is sponsored by Carilion Clinic through a Research Acceleration Program Grant.

The person running this study is Dr. Cassandra Mierisch. Before you can decide whether to take part in the research, you should be told about the possible risks and benefits with this study. This process is known as informed consent. This consent form will give you information about this study and your rights as a research subject. Being in this study is voluntary.

Be aware that the role of the research doctor is different from the role of your personal doctor. Your personal doctor decides how to treat your specific problem in order to help you. The research doctor treats all subjects under a specific protocol to obtain general knowledge that may or may not benefit you. Be sure to ask your doctors questions to help you know more about these different roles.

WHY IS THIS RESEARCH BEING DONE?

The purpose of this research is to evaluate the effect of a patient education program (video) on recovery after surgery, including pain management, wound care, and your satisfaction with your experience immediately after your surgery. There will be 400 subjects taking part, all locally. The length of time you can expect to be in this research is from enrollment until your first follow-up visit after surgery. We will also contact you about a year after your surgery with a few follow-up questions about your recovery.

WHAT WILL HAPPEN IN THIS RESEARCH STUDY?

It is not clear whether the patient education videos actually do improve patient recovery after surgery. For this reason, the education program given to you is assigned using a method called randomization. Randomization means that the group you are in is assigned by chance, like the flip of a coin. Your chance of receiving each educational program is equal.

If you decide to take part, you will first be asked to provide some information about your home medications and complete two 2-5 minute questionnaires. Then you will be randomly assigned to watch one or two six-minute educational videos. You may receive a handout corresponding to the videos. You will have access to this video throughout the study for your review. Your doctor will not know which video you watch. However, if you wish to discuss any of the information presented in the videos with your doctor, you are free to do so. Your doctor is, of course, familiar with all of the topics you may learn about from the video.

After your surgery, you will receive a diary, which will ask you to record details of your recovery for 7 days after surgery. It will also include the same two questionnaires you completed pre-operatively and a knowledge quiz. Your responses are for study purposes only. They will not affect your care in any way.

A study coordinator will contact you by phone twice during the week after surgery to answer any questions you may have about the study and assist with the completion of materials.

Please return the study packet at your first post-operative visit. At that point, a researcher will meet with you again and ask you a few more questions about your experience. You may be contacted by phone with a reminder to return the study packet, if needed.

Finally, approximately one year after your surgery, the researchers will contact you again to ask about whether you have continued to need pain medications since your surgery and, if so, what medication you're taking, how often, and in what doses.

WHAT ARE THE RISKS OF BEING IN THIS RESEARCH STUDY?
The risks of this study are minimal. The risks can be compared to those ordinarily encountered in daily life.

WHAT ARE THE RISKS TO A PREGNANCY OR TO A NURSING CHILD?
If you are planning to get pregnant, you should not be in the study. If you are able to become pregnant and you are sexually active, you are asked to practice an effective method of birth control while in this study. Methods of birth control include total abstinence (no sex), oral contraceptives ("the pill"), an intrauterine device (IUD); Levonorgestrel implants (Norplant), or Medroxy-progesterone acetate injections (Depo-Provera shots). If these cannot be used, contraceptive foam with a condom is recommended. If you are not sure about birth control or whether you could still get pregnant, discuss this with your doctor.

Some patients after surgery will use non-steroidal anti-inflammatories (NSAIDS) to treat pain. Some studies have shown that taking NSAIDS in early pregnancy can increase the rate of miscarriage and birth defects. Taking NSAIDS late in pregnancy places the fetus at risk in other ways and should be avoided. There are reported cases of opioid toxicity in breastfed infants of mothers taking opioid medications.

WHAT ARE THE BENEFITS OF BEING IN THIS RESEARCH STUDY?
The educational programs presented in this study are designed to help patients in their recovery after surgery. Whether they are actually helpful has not been proven.

Although you may not personally benefit from taking part in this study, the knowledge gained may benefit others.

ARE THERE ANY OPTIONS TO BEING IN THIS RESEARCH STUDY?
Your option is to not take part in the study. You will receive the patient education that is part of the usual outpatient surgical experience.

WILL I RECEIVE NEW INFORMATION ABOUT THIS RESEARCH STUDY?
Sometimes new information comes out that may affect your health, welfare, or willingness to stay in a study. If that happens, the researchers will tell you about that

information. They will also tell you about other options for your care. You may need to sign another form with your consent to continue in the study.

WHAT ABOUT CONFIDENTIALITY?
Questionnaires will be completed in a private, confidential room. The completed paper questionnaires and diaries will be kept private in a locked office and in a locked filing cabinet. The questionnaires will be coded with a unique number. Your name will be linked to the code number on a master list of those who take part in the study. This master list will be kept separate from the questionnaires and will be stored in a second locked filing cabinet. This master list will only be used by the researchers or organizations that govern research quality and safety oversight. Your identity will not be used in any sort of published report.

Electronically collected data and research records will be kept private on protected Carilion shared drives. All research data will be coded with a unique number. Your name and medical record number will be linked to the code number on a master list of those who take part in the study. This master list will be kept separate from the research database and will be stored in a locked filing cabinet and/or on protected Carilion shared drives. This master list will only be used by the researchers or organizations that govern research quality and safety oversight. Your identity will not be used in any sort of published report.

Dr. Mierisch is applying to have this study covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child or elder abuse or communicable diseases); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WHAT WILL TAKING PART IN THIS RESEARCH STUDY COST OR PAY?
It does not cost anything to take part in this research study. Information given to you through the educational programs may possibly lead you to purchase supplies that you want to have on hand during your recovery after surgery.

Participants will be provided with a token "thank you" gift, a cup with lid.

WHAT WILL HAPPEN IF I HAVE COMPLICATIONS OR IF I AM INJURED BY THIS RESEARCH STUDY?
If you have a medical problem that happens because you are in this study, you will be able to get treatment. The treatment will be billed to you or your insurer at the usual charge. The study does not make any provisions for the payment of these costs. You will not receive any other financial compensation. However, you do not give up any legal rights to seek compensation for injury by signing this consent form.

WHAT IF I WANT TO STOP BEING IN THE STUDY BEFORE IT IS FINISHED?
Being in this research is voluntary. You may refuse to take part or you may withdraw at any time. Your decision not to take part or your decision to withdraw will not affect your ability to get care from your doctors or from Carilion. The researchers may take you out of the research study for any reason, without your consent, if they feel it is in your best interest. The reason for any exclusion will be explained to you.

ARE RESEARCHERS BEING PAID TO DO THIS STUDY?
This study is supported by a research grant from Carilion Clinic. Some of the investigators, such as the research coordinator, are paid for doing research.

WHO ARE THE CONTACT PERSONS?
If you encounter medical problems, complications or have any questions about the study, you may call the researcher, Allison Bell, during the day at (540)855-1380 or Dr. Cassandra Mierisch at (540)588-8076 daytime, evenings and weekends. If you have questions about your rights as a research subject, you may contact staff of the Carilion IRB at (540) 853-0728.

AUTHORIZATION TO USE YOUR HEALTH INFORMATION FOR RESEARCH:
There is a federal law that protects the privacy of health information. This law is known as HIPAA. HIPAA stands for the "Health Insurance Portability and Accountability Act."

Signing this consent and authorization form means you give permission to the Carilion Principal Investigator for this study and members of the investigator's research team to create, get, use, store and share private or "protected" health information that identifies you for the purposes of this research. If you decide not to give your permission, you cannot be in the study, but you can continue to receive regular care at Carilion.

This is the protected information about you that researchers will use:

- Personal identifiers such as name, telephone number, or medical record number(s).
- Demographic information such as age and gender.

- Current and past medications or therapies, including the dates of surgery and office visits.
- Information from surveys/diaries and questionnaires done for this study.

The research team may share protected information about you with:

- The Carilion Clinic Institutional Review Board, a research protection group that provides ongoing review of the research project.
- Authorized employees of Carilion Clinic who need the information to perform their duties to provide treatment, to ensure the integrity of the research or to do accounting and billing.
- Laboratories and other individuals and organizations that analyze your health information in connection with this research.
- The Food and Drug Administration (if this research is FDA regulated) or other government agencies that oversee research with humans.
- Committees that monitor research data and safety or other groups authorized to monitor the study.

Carilion Clinic and its affiliates are required under law to keep your protected health information private and confidential. However, the individuals or agencies who receive your protected health information may not be required by the Federal privacy law to protect it. They could share your protected health information with others without your permission, if permitted by the laws governing them.

You have the right to stop sharing your protected health information. To end your permission, you must write to the Principal Investigator at the address listed on the first page of this form. If you want the researchers to stop collecting your information for the research, you may be removed from the study. If you are removed from the study, it will not affect your ability to receive standard medical care or any other benefits you are entitled to receive. PHI collected for the research study prior to you ending your permission will continue to be used for the purposes of the research study. Also, the FDA (if involved with your study) can look at your information related to the study even if you end your permission.

You may not be able to see your protected health information in your medical record related to this study until the study is complete. If it is necessary for your care, your protected health information will be provided to you or your physician.

Research information continues to be analyzed or monitored after the study is finished so it is difficult to say when use of your protected health information will stop. There is not an expiration date for this authorization to use and disclose your protected health information for this study.

CONSENT SIGNATURES:

- **Research Subject Box** must be completed.
- **Person Obtaining Consent Box** must always be completed.

RESEARCH SUBJECT: The research study described in this consent form, including the risks and benefits, has been explained to me and all of my questions have been answered. I consent to take part in this research study. My consent is given willingly and voluntarily. I may withdraw my consent at any time. I will receive a signed copy of this consent form.

_____

Printed Name of Research Subject (18 years or older)

_____ _____

Subject's Signature Date

PERSON OBTAINING CONSENT: I certify I was present for the informed consent discussion. The subject or legally authorized representative had an opportunity to ask questions about and appeared to understand the information presented. The subject or legally authorized representative agreed to take part voluntarily in the research and I obtained his/her signature.

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Printed Name of Person Obtaining Consent

_____ _____

Signature of Person Obtaining Consent Date