

VUMC Institutional Review Board
Informed Consent Document for Research

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Study Title: Development and Validation of a Gaze-based Training for Endoscopic Kidney Stone Surgery
Version Date: 2/21/2025
PI: Dr. Nicholas Kavoussi

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:

The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

The purpose of this study is to determine whether or not optical tracking and gaze data can improve surgical education. Currently, there are no objective means of evaluating surgical residents. This study will passively provide information on expert surgeon gaze information to surgical residents during kidney stone surgery. There are no additional risks to the procedure. There is no compensation for participation in this study. The study will conclude immediately at the conclusion of the surgery.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because we are investigating novel ways to improve education for kidney stone surgery. It is hoped that the knowledge gained will be of benefit to others who need treatment of their kidney stones in the future.

You do not have to be in this research study. **You may choose not to be in this study. This is not a treatment study, so there are no alternative treatments.** You may choose not to be in this study without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

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Side effects and risks that you can expect if you take part in this study:

The research consists of performing standard stone surgery which would happen regardless of the research project. We will record optical gaze information of the surgeons during the study. Potential risks of ureteroscopy include pain, bleeding, and infection.

Good effects that might result from this study:

The benefits to science and humankind that might result from this study: It is hoped that the knowledge gained will be of benefit to others who need treatment of their kidney stones in the future.

Procedures to be followed:

If you agree to be in this study, you will undergo the standard ureteroscopy procedure and then be treated in standard fashion postoperatively. The only difference is that we will be collecting surgeon eye-gaze data. There are no other differences in this study compared to patients who routinely undergo this surgery. You will be in the study until the completion of the procedure.

Payments for your time spent taking part in this study or expenses:

You will receive no compensation for your participation in this study

Costs to you if you take part in this study:

There is no cost to you for taking part in this study.

Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Nicholas Kavoussi at 615-343-1317.

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For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:

You may be withdrawn from the study for the following reasons:

- If it is in your best interest.
- If you don't follow the study procedures
- If the study is stopped.

You may also be withdrawn from the study if you do not follow the instructions given to you by the study personnel.

What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

Confidentiality:

Research records will be kept confidential to the extent allowed by law. All study personnel are trained in procedures to ensure patient privacy and confidentiality according to the HIPAA privacy rule. Your study records include information that identifies you and that is kept in research files. We will try to keep this information confidential, but we cannot guarantee it. The data will be stored in a password-protected database with limited access. If data from this study are to be published or presented, we will first take out the information that identifies you.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study, future research, or insurance purposes. Disclosures that you make yourself are also not protected.

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Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:

Study results will be shared with the participant after 1 year follow up visit.

Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

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How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date

Signature of patient/volunteer

Consent obtained by:

Date

Signature

Printed Name and Title

Time: _____

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