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:
You are being asked to take part in this research study because you have selected ureteroscopy for the surgical treatment of your patient's kidney stone(s). We are conducting this study to gather clinical information to help understand the benefits of optical tracking on 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 after completing 10 separate kidney stone surgeries.

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 there are currently no objective metrics measuring surgical competency for kidney stone surgery. Optical tracking has shown to distinguish novice and expert surgeons in phantom models. Additionally, eye gaze information can be relayed to trainees to potentially improve surgical training.

You do not have to be in this research study. You may choose not to be in this study and treat patients based on your professional recommendation. 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.

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Side effects and risks that you can expect if you take part in this study:
None. There may be unknown or unanticipated adverse effects.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study: We may find that optical tracking and gaze information improves surgical education for kidney stones and improves competency for stone treatment, which would have a broad impact on patients.

Procedures to be followed:
For expert surgeons: We will be collecting intraoperative eye gaze data during ureteroscopy. We may be displaying that data as a pointer for the resident to during the surgery. We plan on obtaining data over 10 cases. The eye gaze data will be analyzed postoperatively.

For resident surgeons: As a resident, we will be collecting intraoperative eye gaze data during ureteroscopy. You will be randomized to whether or not you will have access to the expert surgeon's eye gaze information in the form of a pointer during the surgery. The eye gaze data will be analyzed postoperatively. You will also be asked to fill out a NASA-Task Load Index form at the conclusion of each surgery.

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.

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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.

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:

- You elect to treat the stones via an alternant surgical technique.
- 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 the study principal investigator.

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.

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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.

Privacy:
To protect your privacy, we will not release your name.

Study Results:
Study results can be disclosed to you if you request once all data has been analyzed.

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.

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.

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.

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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: _____