INFORMED CONSENT FORM

Official title: Development and Validation of Virtual Laparoscopic Hiatal Hernia Simulator (VLaHHS)

NCT number: NCT06974383

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Title of Study: Development and Validation of Virtual Laparoscopic Hiatal Hernia Simulator (VLaHHS)

Consent to be part of a Research Study
To be conducted at
The University of Texas Southwestern Medical Center
Part 3, Phase III

Key Information about this Study

This study is broken into three phases. This is the third phase of this study. If you decide to take part in this study, you will be asked to perform either of the following two tasks (1) Hiatal hernia dissection and crural closure and (2) Fundoplication on the Virtual Laparoscopic Hiatal Hernia Simulator (VLaHHS) either with a three week training (simulation group) or at specific times without additional training (control group). You will also be asked to take a pre-test, post-test, retention test and the transfer of skill test which will be on a crural repair silicone model and porcine fundoplication model as described in the apparatus section.

Your participation in this study may last up to five weeks. You may spend time away from school or work to participate in this study. You may become anxious or experience some fatigue while performing the simulation test. As a benefit you may also gain some valuable skills performing these skills test.

The procedures involved in this study include a virtual reality-based simulator with both visual and touch feedback.

Information about this form

You may be eligible to take part in a research study. This form gives you important information about the study.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

Please tell the researchers or study staff if you are taking part in another research study.

Voluntary Participation - You do not have to participate if you don't want to. You may also leave the study at any time. If you decide to stop taking part in this research study, it will not affect your relationship with the UT Southwestern staff or doctors. Whether you participate or not will have no effect on your legal rights.

If you are a medical student, fellow, faculty, or staff at the Medical Center, your status will not be affected in any way.

General Information – "Who is conducting this research?"

Principal Investigator
The Principal Investigator (PI) is the researcher directing this study; the PI is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Ganesh Sankaranarayanan, PhD, Department of Surgery at The University of Texas Southwestern Medical Center (UTSW).
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Funding
The National Institute of Biomedical Imaging and Bioengineering, federal agency that promotes scientific research, is funding this study. This organization is providing money to UTSW so that the researchers can conduct the study.

Purpose – "Why is this study being done?"

The purpose of this study is to establish the learning curve and predictive validity of the Validation of Virtual Laparoscopic Hiatal Hernia Simulator (VLaHHS). Two separate tasks (1) Crural closure and (2) Fundoplication of VLaHHS will be tested separately (10 participants per task).

The learning curve of VLaHHS will be established by training subjects in the task over extended period until they reach a plateau. The predictive validity will be established by comparing the training group with a control group with no training by testing their skills on an appropriate simulated surgical task on a crural repair silicone model and porcine fundoplication model as described in the apparatus section.

You are asked to participate in this research study to establish the learning curve and predictive validity of the Validation of Virtual Laparoscopic Hiatal Hernia Simulator (VLaHHS).

The researchers hope to learn the degree to which the simulator can differentiate between two groups of different skill levels.

Information about Study Participants – "Who is participating in this research?"

You are being asked to be a participant in this study because you are either a general surgery resident or attending.

How many people are expected to take part in this study?
This study will enroll approximately 120 study participants. 20 will take part in this phase of the study.

Information about Study Procedures – "What will be done if you decide to be in the research?"

While you are taking part in this study, you will be asked to participate for approximately 7 weeks with the researchers or study staff.

Study Procedures - as a participant, you will perform the following procedures:

If you choose to participate in this study you will be asked to sign an informed consent form before completing any study related procedures. The study procedures are as follows

- You will be randomly assigned (like flipping a coin) or "randomized" into one of the study groups described below:
- *Control Group* –

  - Before the testing session begins, you will receive a guided, hands-on orientation to the task that is being tested. You will then take a pre-test in which you will be asked to perform the task once to mark your baseline performance.
  - No extra or special training. You will continue with your normal medical resident training and will not participate in any other task training.
  - Skill learning will be measured four weeks after orientation and again two weeks later to measure retention.
  - Immediately after post-test, transfer-of-training will be assessed using simulated crural repair or fundoplication model. The transfer study will be conducted either at the UTSW Simulation Center or at the Artificial Intelligence and Medical Simulation (AIMS) Lab in south campus.
- *Simulation Group* –
  - Before the testing session begins, you will receive a guided, hands-on orientation to the task that is being tested. You will then take a pre-test in which you will be asked to perform the task once to mark your baseline performance.
  - You will perform the tasks on VLaHHS for an hour a day for a maximum of no more than three weeks (3 weeks x 5 days = 15 sessions). In each session of no more than an hour, subjects will repeat the task five times.
  - Skill learning will be measured immediately following training (post-test) and again after two weeks to measure retention.
  - Immediately after post-test, transfer-of-training will be assessed using simulated crural repair or fundoplication model. The transfer study will be conducted either at the UTSW Simulation Center or at the Artificial Intelligence and Medical Simulation (AIMS) Lab in south campus.

Your performance on the tasks will be videotaped. The videotaping will focus only on your hand and the VR display, and any identifying information such as your face will not be captured.

Your performance during this research study will not be shared with individuals in authority and will have no bearing on your residency performance.

Could your participation end early? There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:
- The researcher believes that it is not in your best interest to stay in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

Risks – "What are the risks of participation in the research?"

You may experience time away from work or school while you undergo test sessions. You may also experience some anxiety while preforming the tests or minor muscle fatigue from standing up during the simulation.

What if a research-related injury occurs?
The researchers have taken steps to minimize any injuries while taking part in this study. There are no risk of injury to participants in this study. In the event of a research-related injury, please immediately contact the Principal Investigator or another research staff member. See the section "Contact Information" for phone numbers and additional information. You may also need to tell your regular doctors.

If you are injured or made sick from taking part in this research study, medical care will be provided. This care may be billed to you or your insurance. We have no plans to give you money if you are injured. The investigator can provide you with more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed as a result of being in this study.

Benefits – "How could you or others benefit from your taking part in this study?"

The possible benefit of your participating in this study could be the gaining of skills as they are being performed during the training sessions on the simulator. There is no guarantee or promise that you will receive any benefit from this study.

We hope the information learned from this study will benefit other surgeons in the future.

Payments – Will there be any payments for participation?

You will be paid up to $380 if you are in the simulation group and up to $80 if you are in the control group. Payment will be made as follows:

- Simulation group: pre-test- $20, post-test- $20, retention-test $20, training $20/each session for a maximum of 15 sessions, transfer test $20 – Total of $380/subject
- Control group: pre-test- $20, post-test- $20, retention-test $20, transfer test $20 – Total $80/subject

These payments are to help cover your expenses for coming to this study visit(s). You will be issued a UT Southwestern Greenphire ClinCard, which can be used as a credit or debit card. Compensation will be credited to the card after completion of the study visits. Your name, address, date of birth and social security number will be shared with a third-party solely for the purposes of compensation processing. Your social security number is needed to process your payments. Study payments are considered taxable income and are reportable to the IRS. Should you decide not to provide your social security number, or your social security number does not match the name on file with the IRS, your study participation payment will be decreased in accordance with the current IRS tax rate. All information will be stored in a secure fashion.

Please note that if you are on record as owing money to the State of Texas, such as for back child support or a delinquent student loan, the payment may be applied to that debt.

An IRS Form 1099 will be sent to you if your total payments are $600 or more in a calendar year, unless it's a reimbursement.

Confidentiality – How will your records be kept confidential?

Information we learn about you in this study will be handled in a confidential manner, within the limits of the law. If we publish the results of the study in a scientific journal or book, we will not identify you. The Institutional Review Board and other groups that have the responsibility of monitoring research may want to see study records which identify you as a subject in this study.

Contact Information – Who can you contact if you have questions, concerns, comments or complaints?

If you have questions now, feel free to ask us. If you have additional questions, concerns, comments or complaints later or you wish to report a problem which may be related to this study please contact:

Primary contact:
Dr. Ganesh Sankaranarayanan, PhD can be reached at 206-734-7458

If primary is not available, contact
Dr. Daniel Scott, MD can be reached at 214-648-3792

The University of Texas Southwestern Medical Center Human Research Protection Program (HRPP) oversees research on human subjects. HRPP and Institutional Review Board (IRB) representatives will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer. You can contact the HRPP by calling the office at 214-648-3060.

Research Consent & Authorization Signature Section

If you agree to participate in this research and agree to the use of your protected health information in this research, sign this section. You will be given a copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE FOLLOWING STATEMENTS ARE TRUE:

- You have read (or been read) the information provided above.
- Your questions have been answered to your satisfaction about the research and about the collection, use and sharing of your protected health information.
- You have freely decided to participate in this research or you are voluntarily giving your consent for another person to participate in this study because you believe this person would want to take part if able to make the decision and you believe it is in this person's best interest.
- You understand that a copy of this signed consent document, information about this study, and the results of any test or procedure that may affect your medical care, may be included in your medical record. Information in your medical record will be available to health care providers and authorized persons including your insurance company.
- You authorize the collection, use and sharing of your protected health information (another person's protected health information) as described in this form.

Adult Signature Section

Printed Name of Participant	Signature of Participant	Date	Time AM PM
Printed Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date	Time AM PM

Blind or Illiterate Signature Section *At the time of consent, also complete this section if consent is obtained from an individual who is unable to read and/or write but can otherwise communicate and/or comprehend English (e.g., blind, physically unable to write, etc.)*

Declaration of witness:

By signing below, I confirm I was present for the entire consent process. The method used for communication (e.g., verbal, written, etc.) with the subject was: _____ .

The specific means (e.g., verbal, written, etc.) by which the subject communicated agreement to participate was: _____.

Printed Name of Witness	Signature of Witness	Date	Time AM PM