CEDARS-SINAI MEDICAL CENTER

CONSENT FORM FOR RESEARCH

RIGHTS AS A HUMAN RESEARCH PARTICIPANT

- You have the right to make a voluntary decision to participate in this research study.
- If you have questions, discuss them with the investigator before you agree to participate. You have the right to ask questions at any time and have them answered as soon as possible.
- You have the right to take time to review this research consent form carefully. You should discuss it with others, and if appropriate seek a second opinion, and make an informed decision.
- You have the right to be informed of significant new findings related to this research study which may affect your willingness to continue participating in this study.
- You have the right not to participate or to withdraw from this research study at any time without any penalty or loss of benefits to which you would be entitled outside of the study. Choosing so will not change the quality of care you receive at Cedars-Sinai Medical Center (CSMC).

PROSPECTIVE DATA COLLECTION & ANALYSIS – LAPAROSCOPIC ROBOTIC-ASSISTED NON-MESH INGUINAL HERNIA REPAIR

1. WHO IS CONDUCTING THIS RESEARCH STUDY?

Principal Investigator: Dr. Shirin Towfigh – (310) 358-5020

After hours contact: Dr. Shirin Towfigh – (310) 358-5020

2. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

Before you decide whether or not to take part in Dr. Towfigh's study, it is important for you to understand why the study is being done and what is required of you. Please take the time to read this informed consent carefully and discuss it with friends and relatives if you wish. Ask Dr. Towfigh or her staff questions if

there is anything that is not clear or if you would like more information about the study. Take your time to decide whether or not to volunteer to be included in this study for research purposes.

The purpose of this study is to evaluate the feasibility of laparoscopic robotic-assisted tissue repair for primary indirect inguinal hernia.

3. WHY AM I ASKED TO PARTICIPATE?

You are being asked to take part in this research study because you have an inguinal hernia and are scheduled to undergo robotic-assisted laparoscopic non-mesh inguinal hernia repair by Dr. Towfigh.

4. HOW MANY PEOPLE WILL PARTICIPATE?

The medical records of about 20 patients at CSMC will be reviewed as part of this observational study.

5. HOW LONG WILL I BE IN THE STUDY?

We think your medical records will be reviewed for about 5 years.

6. WHAT STUDY PROCEDURES ARE INVOLVED?

If you take part in this study, you will be asked to give us permission to review your medical records as it relates to your robotic-assisted laparoscopic inguinal hernia repair without mesh. You are not required to undergo any additional procedures or make any additional office visits to participate in this study. If you elect to participate in this study, you may have your operation performed at a non-CSMC site. Data from any non-CSMC site relevant to your care by Dr. Towfigh, will already be stored in your health records with Dr. Towfigh, therefore, no additional authorizations will be needed in order to obtain your data. Private health information to be reviewed in your medical records will include:

- all hernia-related imaging including x-ray, ultrasound, CT, and MRI
- doctors' records
- hospital records
- pathology reports

The following private information about you will be placed in the research study records:

- Name;
- Telephone and/or fax numbers;
- Medical record numbers;
- Dates (treatment dates, birth date, date of death); and
- Codes assigned in connection with the study to only your information that could be used to identify you.

7. WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS?

There are no physical risks to you expected from taking part in this research study. However, the risk for breach of confidentiality exists in any research. See the section, "How will my Private Information be Kept Confidentiality?" for more information about how the confidentiality of your private information will be protected.

8. ARE THERE DIRECT BENEFITS IN TAKING PART IN THE STUDY?

You should not expect to benefit from taking part in this research study.

9. HOW CAN MY PARTICIPATION BENEFIT OTHERS?

While no direct benefit is expected, we hope the information learned from research gathered from this study will benefit future patients with inguinal hernias. Research from this study will help us learn and develop better treatment and operative techniques, resulting in decreased hospital stay and post-operative complications.

10. ARE THERE ANY OTHER OPTIONS?

Your participation is voluntary and you can choose to not participate in this study. Participation in this study is absolutely voluntary and will not affect the treatment received at Beverly Hills Hernia Center or CSMC. Your medical care will not be changed in any way as a result of this decision.

11. HOW WILL MY PRIVATE INFORMATION BE KEPT CONFIDENTIAL?

CSMC values and respects your private information. Federal and state laws protect

your privacy. Every reasonable effort will be made to keep your records confidential, such as storing your private information in a secure location where only authorized individuals will have access to it. Investigators will assign a unique code to your research information so that people who see the coded data will not be able to identify you.

If information from this study is published, presented at scientific meetings, or used for teaching, your name and other personal information will not be used.

People inside and outside of CSMC may need to see your information for this study. Information collected about you during the course of this research may be subject to inspection by accrediting agencies, government and regulatory groups (e.g. Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), etc.), safety monitors, and companies that sponsor the study. These agencies are responsible for the oversight of this research.

What information will you learn about me as part of this research?
You are being asked for your authorization to allow the research team acting under the direction of Dr. Towfigh to review your medical records and collect health information about you as described under the section "What Study Procedures are Involved?"

Who will have access to your private information?
Your private information will be used by and/or shared with Dr. Towfigh and her research team as part of the research study. Reasonable efforts will be made to assure that the research team will have access only to the private information about you that is minimally necessary to conduct the research study. Additionally, the following parties may receive information about you:

• Medical and other health care professional students who are assisting with tasks for the research study

How long will my authorization for use of private information be in effect?
By signing this document, you authorize the use and sharing of your private information until 07/01/2035.

Withdrawal of Authorization
You have the right to withdraw your authorization for us to use your health information at any time. You must write to Dr. Towfigh to withdraw your authorization. The mailing address is: 450 N. Roxbury Dr. Suite #224, Beverly Hills, CA, 90210. Any information already obtained at the time you withdraw your authorization may continue to be used as necessary to ensure study integrity. For

example, it may be necessary to continue to use your information to conduct investigations or to report adverse events.

Further disclosure (sharing) of your private information
Your private information will be shared by Dr. Towfigh and CSMC only as needed for the research study. CSMC makes an effort to ensure that recipients of your information take steps to maintain the confidentiality of your private information and only receive the information that they need, and not more. Certain individuals or organizations that may receive your private information could though, in very limited circumstances, reveal it for purposes not related to the research study. This would be an unauthorized and illegal disclosure (sharing) of your information. In this study, Dr. Towfigh does not anticipate that this will happen. Moreover, in California, the law prohibits such further disclosure of private information without another signed authorization from you (unless the law requires the particular disclosure, such as to report suspected child abuse).

Notice of Rights and Other Information
You have a right to receive a copy of this Consent and Authorization Form.

If you are not comfortable with how your private information might be used, you can choose not to give your authorization for us to use this information. This choice is a very important right that you have. However, if you do not give us the authorization to use this information for this research, you will not be able to participate in the database. For more information about your rights as a research participant, see the *Rights As A Human Research Participant* box at the beginning of the consent form.

If you have any questions after reading the following sections, please contact Dr. Towfigh at the number listed in Section One. She is required by law to protect your private information. By signing this document, you authorize the use or disclosure of your private information in connection with the research study as described above.

12. WILL I BE PAID?

You will not be paid for taking part in this research study.

13. WHAT IF I HAVE QUESTIONS OR PROBLEMS?

If you have questions or concerns about this research, please contact Dr .Towfigh.

If you have questions regarding your rights, concerns, or complaints about taking

part in this study, please contact:

CSMC Institutional Review Board (IRB)
Phone: (310) 423-3783
Email: ResearchConcerns@cshs.org

The CSMC IRB has been established to review, approve, and monitor all human research at CSMC with the purpose of minimizing risks and protecting the rights and welfare of research participants.

14. CONSENT & AUTHORIZATION PROVISIONS

If you sign this form below, it means that:

(1) You have carefully read and understood the information presented in this informed consent form;
(2) The information concerning the research study and its involved procedures has been fully explained to you and your questions have been answered to your satisfaction;
(3) You have received all of the information you desire regarding your participation in the research study;
(4) You have considered the potential risks, anticipated benefits and alternatives (and their relative risks and benefits) of participation;
(5) You are voluntarily agreeing to participate in this research study; and
(6) You understand that by consenting to participate in the research, you are not giving up any of your legal rights.

If you have any additional questions during the course of your involvement in the research, please contact the investigator(s) and/or the IRB Office at any time.

We will give you a copy of this signed and dated consent form.

SIGNATURE BY THE SUBJECT:

Name of Subject (Print)	Signature of Subject	Date of Signature

SIGNATURE BY THE INVESTIGATOR:
I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

Signature of the Investigator Who Obtained Consent	Date of Signature

SIGNATURE BY THE INTERPRETER/WITNESS
(Signature of an interpreter is only required when a non-English speaking subject is consented with the assistance of an interpreter and an IRB-approved 'short form.' The witness may be any person who is conversant in both English and the

language of the Non-English speaking subject, such as the interpreter (the certified hospital interpreter), study staff, a family member, or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.)

Signature of Interpreter/Witness Date of Signature

Distribution instruction for investigators:

The signed Consent and Authorization form, should be distributed to:

1) Subject
2) Principal Investigator's research records (original)