



CEDARS-SINAI MEDICAL CENTER

ASSENT FOR TEENS 16 YEARS OF AGE/PARENTAL PERMISSION*/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).

HERNIA DATABASE RESEARCH—PROSPECTIVE & RETROSPECTIVE

*This form will also serve as a Permission Form for your child to participate in this research. In this case, “You” refers to “Your child” and “you”

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 DATA REGISTRY?

Before you decide whether or not to take part in Dr. Towfigh’s observational

database, 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 database. Take your time to decide whether or not to volunteer to be included in this database for research purposes.

The purpose of this data registry is to collect data from patients with hernia or hernia-related problems. We hope this registry can be useful for future research studies about hernias and hernia-related problems. We hope that the establishment of this registry will increase our knowledge and give us a better understanding so that we may determine the best kinds of therapy for patients with hernias.

3. WHY AM I ASKED TO PARTICIPATE?

You are being asked to take part in this research study because you have a hernia or a hernia-related problem and are being treated by Dr. Towfigh.

4. HOW MANY PEOPLE WILL PARTICIPATE?

The medical records of at least 3000 patients will be reviewed as part of this database research study. The patient volume will grow on an annual basis.

5. HOW LONG WILL I BE IN THE STUDY?

We wish to analyze your medical records for at least 5 years.

6. WHAT STUDY PROCEDURES ARE INVOLVED?

If you take part in this database, you will be asked to give us permission to review your medical records. You are not required to undergo any procedures, or make any additional clinic visits to participate in this database. Patients electing to participate in this database may have their 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 record will include:

- all hernia-related imaging including x-ray, ultrasound, CT, and MRI
- doctor's records
- hospital records

- pathology reports

The following private information about you will be placed in the research study Linking List which will contain only your contact information below and a unique numerical identifier which will be used on the Data Abstraction tool containing health information. This Linking List will be kept on a secure, encrypted laptop in the Principal Investigator's office and any hard copies will be locked in Dr. Towfigh's office.

- Name;
- Telephone numbers;
- Fax numbers;
- Medical record numbers;
- Electronic mail address;
- Dates (treatment dates, birth date, date of death)

7. WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS?

There are no physical risks to you expected from taking part in this database. 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 database will benefit future patients with hernias or hernia-related complications. Research from this database will help us learn and develop better treatment and operative techniques, reduce the diagnosis time of hernias or hernia-related complications, and create a more streamlined process for patients with hernia or hernia-related complications.

10. ARE THERE ANY OTHER OPTIONS?

Your participation is voluntary and you can choose to not participate in this

database. 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, encrypted laptop with password protection known only by 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 on the Data Abstraction tool 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 may need to see your information for this study. Information collected about you during the course of any research may be subject to inspection by accrediting agencies, government and regulatory groups (e.g. Office for Human Research Protections (OHRP), etc.), data safety monitors, and any companies that may 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 not be used by and/or shared with Dr. Towfigh and her research team as part of research studies. 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 only as needed for the database. 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 database research study as described above.

12. WILL I BE PAID?

You will not be paid for taking part in this database.

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

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;
- (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 principal investigator.

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

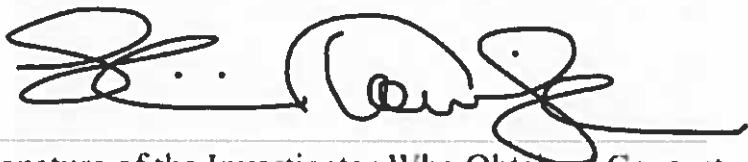
IRB No: Pro00037222

Approval Date: 4/20/2015

Expiration Date: 3/31/2016

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

IRB No: Pro00037222

Approval Date: 4/20/2015

Expiration Date: 3/31/2016

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

IRB No: Pro00037222

Approval Date: 4/20/2015

Expiration Date: 3/31/2016

SIGNATURE BY THE SUBJECT'S PARENT/GUARDIAN (If applicable)

By providing my signature below, I consent for the participation of myself and give permission for the participation of my child, _____, in the research study described in this document.

Parent/Guardian Name (Print)

Signature

Date of Signature

IRB No: Pro00037222

Approval Date: 4/20/2015

Expiration Date: 3/31/2016

Distribution instruction for investigators:

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

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