INFORMED CONSENT FORM

Informed Consent form to participate in a research project – Focus Group

Study Title: Feasibility Study Using Hospitals Participating in the American Hernia Society Quality Collaborative (AHSQC) to Assess Patient Reported Outcomes after Ventral Hernia Repair with Mesh

Institution: The U.S. Food and Drug Administration **Principal Investigators**: Anchal Kaushiva, Karen Ulisney, George Gibeily, Ting-Hsuan Lee

What is this about?

You are invited to participate in a study to learn about patient outcomes to improve quality treatment for hernia patients. You are invited to participate *as you have had a hernia treatment and are over 18 years of age*.

Study purpose

The Americas Hernia Society Quality Collaborative (AHSQC) was established in 2013 as a quality improvement program to study and improve health outcomes for hernia patients. This is intended to be accomplished through patient-centered data collection in a registry. One hundred and fifty hospitals currently contribute data to the registry. The registry has a portal that allows patients to enter data directly into a patient-reported outcome (PRO) tool (a survey). However, the frequency of data collection, the amount of missing data, and the content appropriateness of the PRO tool is unknown. This study plans to further enhance the content of the existing PRO tool, and determine the value of the data captured by the PRO tool

to be used for device surveillance and regulatory decision making. This study will contribute to the quality improvement process for hospitals and other providers participating in the AHSQC.

Study procedure

You will be part of a group discussion talking about the experiences of your hernia treatment and outcomes. Your input is important to us, and your contribution is appreciated. Each discussion group (called a focus group) will consist of 5 to 8 participants. There will be one researcher leading the discussion and asking open-ended questions about what is important to you and how you felt after hernia treatment, a survey will also be handed to you for discussion of the survey design. One note-taker may be present to observe and record the discussion through notes and audio recording. The focus group will take 1.5 to 2 hours.

We will conduct and document interviews and focus groups with other hernia patients in hospitals nationwide.

Risk and discomforts

We do not anticipate that taking part in this research study will put you at risk or discomfort. There are no right or wrong answers, and you may skip through any questions you don't want to answer. Participation is voluntary; you may choose to withdraw from the study at any time without penalty. Personal identifiable information you provide will be kept secure by the research team.

There are no direct benefits in participating in the study, yet your participation will contribute to the quality improvement effort for hernia treatment, and the generalizable knowledge in the field of ventral hernia.

Compensation

No compensation will be provided to you for taking part in the study.

Confidentiality

Efforts will be made to keep study participant's personal information confidential. Personal identifiers will be replaced with unique ID numbers, and the interview and focus group transcripts will be de-identified. Participant's name will not be used in the written reports or publications which may result from this research.

Subject identifiers such as consent forms will be stored in secure file cabinets, or encrypted with a password if it is an electronic document, and can only be accessed by the project team. Identifiable information will be kept confidential unless required by law. The recordings of the

interview and focus group discussions will be deleted after transcribing. Data will be analyzed and securely stored in the FDA White Oak Campus.

Contacts

If you would like to know more about this study, or have any questions or concerns about participation in this study, the principal investigator conducting this study is Anchal Kaushiva from the Center for Devices and Radiological Health in the US Food and Drug Administration. You may contact her at MedSunHernia@fda.hhs.gov You may also contact Joyce Lee, the study researcher at ting-hsuan.lee@fda.hhs.gov or by phone at 240-402-0716.

If you have questions about your rights as a research participant, you may contact the Office of Good Clinical Practice Office of Special Medical Programs, Office of the Commissioner Food and Drug Administration 10903 New Hampshire Ave., WO32-5129 Silver Spring, MD 20993 (301) 796-8340. You will receive a copy of this form to keep for your records. If you wish to file complaints or report possible coercion to participate in this study, please contact the RIHSC Chair Jeffrey DeGrasse, PhD, (240) 402-4929, Jeffrey.DeGrasse@fda.hhs.gov Or FDA Human Protections Administrator: Rakesh Raghuwanshi 301 7964769, rakesh.raghuwanshi@fda.hhs.gov

You have not waived any legal right to which you are legally entitled by signing this form.

Consent

Your signature documents that you have read the above information and understood the purpose of the study and the potential risks and benefits involved. Your signature documents your permission to take part in this research.

Printed Name of Study Participant	**Signature** of Study Participant	Date

Signature of Person Obtaining Consent	Date