



INFORMATION FOR PATIENTS

This information sheet tells you how your surgeon's participation in the Abdominal Core Health Quality Collaborative (ACHQC) aims to improve care for you and many other patients with hernia disease and diseases of the abdominal wall or abdominal core. Your surgeon will include your personal health information (such as your name, birthdate, address, and health care treatment) in the Abdominal Core Health Quality Collaborative confidential, secure data registry unless you request (as explained below) that your personal health information not be included. We hope you will allow your information to be included because doing so will help improve the quality of care for patients with abdominal core health issues such as hernia, tumors, and infections and help improve the ways surgeons prevent hernias from forming.

- **What is the Abdominal Core Health Quality Collaborative (ACHQC)?**

->The ACHQC is a large group of surgeons committed to improving the quality of care for patients who have abdominal core health problems and often undergo surgery for those problems. These surgeons are also committed to reducing the chance of abdominal core health problems from forming in the first place.

- **How does it work?**

-> During the routine care of your abdominal core health problem, your surgeon collects information about you and how you do after surgery as part of your confidential health care records.

-> Your surgeon will input information about you and your surgery into a confidential, secure registry maintained by the ACHQC. Only your surgeon, the ACHQC, and, in very limited circumstances, the United States Food and Drug Administration (FDA) will have access to any information that identifies you.

-> Your identifiable personal health information (such as your name, birthdate, address, and health care treatment information) must be entered into the registry in order to make it useful for your surgeon's and the ACHQC's quality improvement efforts and so that the scientific validity of registry data can be tested. If available, your surgeon will also enter your email address, cellular phone number, and mailing address. Your personal health information, in an anonymous form (meaning your identity cannot be matched to your information), is combined with anonymous information from hundreds (or thousands) of hernia patients like you so that it can be used by those interested in improving hernia care other than your surgeon and the ACHQC.

-> Your data may be provided to the FDA for the purpose of informing the use of particular medical devices used to care for patients with abdominal core problems and the prevention of those problems. Data provided to the FDA is typically submitted in a de-identified form, although occasionally FDA may request access to your confidential health information under its regulatory authority to monitor public health. This information may not be

completely anonymous; however, it will be kept in a secure location and any public reports or publications that are generated from the registry for FDA purposes will not contain information that will allow you to be personally identified. Any release of patient protected health information will only be performed consistent with applicable local, state and federal laws, regulations and institutional policies.

-> ACHQC information, in completely anonymous form, may be used by multiple groups interested in abdominal core health problems including health care providers, hospitals, industry, insurance companies and researchers.

-> There is no monetary compensation to you for having your information included in the ACHQC registry.

-> We anticipate about 9,000 to 12,000 patients' information being entered into the registry each year, although the number of patients may increase as more surgeons participate in the registry.

-> The ACHQC will keep your personal health information in the registry for at least 15 years to help know what happens after your hernia operation or other surgery or treatment on a long term basis. When your information is no longer maintained as part of the registry, it will be deleted in a secure manner consistent with applicable privacy and patient information requirements. Your personal health information in a de-identified (anonymous) form may be maintained indefinitely by those who have used the anonymous registry data.

- **How does this benefit patients like me?**

-> The information gathered from many surgeons and patients is much better than information a single surgeon has about abdominal core health problems with regards to best technique and best use of mesh for particular patients and particular abdominal core health issues.

-> This information is used to improve the quality of care by finding the best ways to minimize complications, pain, and the chance of your problem coming back.

-> Although the ACHQC is not a research study, having your information included in the ACHQC registry can make you eligible for future research studies. You may be contacted by your surgeon or the ACHQC if you are eligible for future research studies, and you can find more information on www.achqc.org.

- **What are the risks involved?**

-> Only your surgeon, the facility where your surgery occurred, the ACHQC and in rare instances FDA will have access to your personal health information input into the registry in an identifiable form. The main risk to you for having your information entered into the ACHQC registry is that your personal health information is unintentionally disclosed to persons who are not authorized to know your information. Multiple industry-standard safeguards are in place to prevent this, similar to the safeguards hospitals use to protect confidential health information during routine care of patients.

-> No system that protects confidential personal health information is 100% effective. In the unlikely event that your information is exposed, you will be personally notified of the incident and appropriate actions will be taken to limit potential risks to you.

-> Your participation in the registry is completely voluntary. Not including your information in the ACHQC registry will not have an impact on your care.

-> If you do not wish to have your information included in the ACHQC registry for quality improvement in your care, please inform your surgeon or contact ACHQC (see information, below; If information already has been collected, it will remain in the registry, but no new information will be collected after 30 days of your notifying your surgeon or ACHQC of your decision not to participate).

- **What can I do to help?**

-> A very important part of your surgeon's care of you and of the ACHQC is finding out how your abdominal core affects *your* life before and after surgery.

-> In addition to clinic visits with your surgeon to follow your progress, your surgeon and the ACHQC may use different ways to follow your progress after surgery including phone calls, email, text messages, or regular mail. If you provide your email address or cellular telephone number, your surgeon and the ACHQC may send you emails or a text messages with a link to a confidential questionnaire for you to complete. You can choose not to receive emails or text messages as described below. Completed questionnaires become part of the anonymous data that ACHQC uses to improve the quality of care for hernia patients. The email will come from ACHQC.org; please don't delete or 'junk filter' this email.

-> You may be asked to complete a follow up questionnaire a few times over the next several years which helps your surgeon and the ACHQC see how you are doing.

- **Will I receive email and other electronic communication?**

-> Unless you choose not to participate in the ACHQC (see below), emails and text messages asking you to complete an ACHQC questionnaire may be sent to you in an unencrypted format and will have no additional personal information about you, other than possibly that you are a patient of your surgeon (the questionnaire itself will be completed on a secure portal to the ACHQC registry).

-> In deciding if you want unencrypted emails or unencrypted text messages to be sent to you, you should consider that communication of protected health information by unencrypted email or unencrypted text message involves potential privacy and security risks. Specifically, unencrypted email and text message transmissions can be intercepted in transmission or misdirected, allowing third parties to view the information. You should also consider that your cellular telephone service provider may impose a data or other charge on you to receive a text message. You should consider asking that any communication of sensitive information be completed by telephone or mail. If you do not wish to receive email or text messages concerning the ACHQC and questionnaires about your hernia, please inform your surgeon or contact ACHQC (see information, below).

- **What if I have questions or choose not to participate in the ACHQC?**

-> Should you have any questions, your surgeon can help provide answers for you. General information, registry updates, and progress of the ACHQC can be found at www.achqc.org. You can also send an email to patienthelp@achqc.org or call (720) 773-7590 any time with questions about the registry.

-> If you do not want your personal health information included in the ACHQC database or you do not want to receive emails, text messages, or other communications from ACHQC, please inform your surgeon or contact ACHQC (by email to patienthelp@achqc.org or call (720) 773-7590).