



"I personally want to thank you in advance for allowing us to participate in this quality collaborative. Through your inclusion we can help improve the care that we provide to all of our patients including you." **-Dr. Harris**

## INFORMATION FOR PATIENTS

This information sheet tells you how Dr. Harris' 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. Dr. Harris 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 hernia, abdominal wall, and abdominal core patients.

- **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 undergo hernia, abdominal wall, and abdominal core surgery.

- **How does it work?**

-> During the routine care of your hernia, Dr. Harris collects information about you, your hernia, and how you do after hernia surgery as part of your confidential health care records.

-> Dr. Harris will input information about you and your surgery into a confidential, secure registry maintained by the ACHQC. Only Dr. Harris, 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, birth date, 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, Dr. Harris 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 of thousands of hernia patients like you so that it can be used by those interested in improving hernia care other than Dr. Harris 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 hernias. 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.

- **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 hernias with regards to best technique and best use of mesh for particular patients and particular hernia types.

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

- **What are the risks involved?**

-> Only Dr. Harris, 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.

-> 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 hernia care, please inform Dr. Harris' staff 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 Dr. Harris or ACHQC of your decision not to participate).

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

-> A very important part of Dr. Harris' care of you and of the ACHQC is finding out how your abdominal wall affects *your* life before and after hernia surgery.

-> In addition to clinic visits with Dr. Harris to follow your progress, the ACHQC may use different ways to follow your progress after hernia repair including phone calls, email, text messages, or regular mail. If you provide your email address or cellular telephone number, 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 Dr. Harris and the ACHQC see how you are doing.

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

-> Should you have any questions, Dr. Harris' office staff can help provide answers for you. General information, registry updates, and progress of the ACHQC can be found at [www.achqc.org](http://www.achqc.org). You can also send an email to [patienthelp@achqc.org](mailto: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 Dr. Harris' office staff or contact ACHQC (by email to [patienthelp@achqc.org](mailto:patienthelp@achqc.org) or call (720) 773-7590).