CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

TITLE: **Outcomes of Component Seperation Hernia Repair**

PRINCIPAL INVESTIGATOR: Dinakar Golla MD
UPMC Department of Surgery
Division of Plastic Surgery
200 Lothrop Street, Pittsburgh, PA 15213
Phone: 412.648.9670

SOURCE OF SUPPORT: No Support

Why is this study being done?

The purpose of this research is to evaluate how patients who have had component separation hernia repair don over time. We are asking 100 patients who have had this type of hernia repair surgery to participate in this research study.

What are the procedures of this study?

If you agree to participate in this research study, you will authorize the members of this research team to look at your medical records and record information related to the history of your hernia repair. You will also be asked to complete a 15-20 minute interview, either over the phone or in person at one of your clinic visits, each year for 7 years. This interview will be conducted by Dr. Golla or Eric Begly from our office, and will ask about your physical well-being, whether your hernia has returned, your ability to do your job and routine household tasks, your mood and your overall quality of life. This will be the same questionnaire that we will ask of each patient. We will conduct this interview yearly after the surgery. If you are unable to answer questions about a recurrence of the hernia and feel more comfortable with being seen, we will offer you to be seen in our office to answer the questions in person. We will keep the information that we have recorded from your medical record, and compare this to the information you give us during these phone interviews.

What are the possible risks and discomforts of this study?

There is little risk involved in this study. No invasive procedures or medications are included. The major potential risk is a breach of confidentiality, but we will do everything possible to protect your privacy. To protect your privacy and confidentiality, we will label all of the information you give us and the information we record from your medical record with a code

number. This information will not be labeled with your name or anything that would directly identify you. Please note, just as with the use of your medical information for health care purposes, we cannot guarantee its privacy.

Will I benefit from taking part in this study?
You will receive no direct benefit from participating in this study.

Are there any costs to me if I participate in this study?
There are no costs to you for participating in this study.
.
Will I be paid to participate in this study?
No. There will be no payment for participating in this study.

Will anyone know that I am taking part in this study?
All records pertaining to your involvement in this study are kept strictly confidential and any data that includes your identity will be stored in locked files and will be kept indefinitely. Your identity will not be revealed in any description or publications of this research. They will be all kept in our administrative office along with our other charts and will only be accessible by members of the research team.

It is possible that authorized representatives from the University of Pittsburgh Research Conduct and Compliance Office may review your data for the purpose of monitoring the conduct of this study. In very unusual cases, your research records may be released in response to an order from a court of law.

How will the privacy of my medical record information be protected?
Several procedures have been put into place to protect the privacy of your medical record information. Your data will be coded with a number instead of a name and secured on a UPMC hard drive that is passcode encrypted. Also, charts for the study will be secured in the office in a separate area and will be destroyed as soon as the study is finished.

May I withdraw, at a future date, my permission for participation in this research study?
Yes. To do so, you must contact the investigators who are listed on the first page of this consent form. If you withdraw from this study, we will, at your request, destroy the identifiable information we have obtained.

Is my participation in this study voluntary?
Your participation in this study is completely voluntary. You may refuse to take part in it, or you may stop participating at any time, even after signing this form. Your decision will not affect your current and future relationship with, or the care you receive from, the University of Pittsburgh Medical Center or the University of Pittsburgh.

How can I get more information about this study?
If you have any further questions about this research study, you may contact the investigators

listed at the beginning of this consent form. If you have any questions about your rights as a research subject, please contact the Human Subjects Protection Advocate at the University of Pittsburgh IRB Office, 1.866.212.2668.

PARTICIPANT'S CERTIFICATION

- I have read the consent form for this study and any questions I had, including explanation of all terminology, have been answered to my satisfaction. A copy of this consent form will be provided to me.
- I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that those questions will be answered by the researchers listed on the first page of this form.
- I understand that my participation in this study is voluntary and that I am free to refuse to participate or to withdraw my consent and discontinue my participation in this study at any time without affecting my future relationship with this institution.
- I agree to allow my identifiable medical record information to be used for the purposes described above.
- I agree to participate in this study.

_____ _____

Participant's Signature Date

CERTIFICATION OF INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about this study have been answered, and we will always be available to address future questions as they arise.

_____ _____

Printed Name of Person Obtaining Consent Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date