The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: Comparative Assessment of Three-dimensional vs. Conventional Laparoscopy in a Total Colectomy model for Ulcerative Colitis

Sponsor: Olympus Corporation

Principal Investigator: Emre Gorgun MD (216-444-1244)

Study Coordinators: Linda Libertini (216-445-4148) Denise Rose (216-445-4523)

You are being invited to participate in a research study. A research study is designed to answer specific questions about new ways to prevent, detect, and treat disease. Being in a research study is different from being a patient. The purpose of this document is to provide a written summary of the discussion and exchange of research information you had with the research team. It is also for use as a reference during the study.

Please note:

- **You are being asked to participate in a research study**
- **Ask as many questions as needed so you can make an informed decision.**
- **Carefully consider the risks, benefits, and alternatives of the research**
- **Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at any time.**

1. INFORMATION ON THE RESEARCH

Why is the research study being done?
The purpose of this research study is to examine the difference between 2 methods of viewing your laparoscopic surgery. One uses the "2D" method and one the "3D" method. The 3D method offers potential benefits of depth perception and orientation over the 2D method. This research study will investigate if these potential advantages of 3D offers any benefit when compared to using the 2D method.

Laparoscopic total colectomy is a surgical procedure that is considered standard of care when medically indicated and will require anesthesia. You will receive the same standard of care treatment whether or not you decide to participate in this study.

The Olympus HD 3D Laparoscopic Surgical Video System has been approved by the Food and Drug Administration (FDA) for use for this surgical use. 'Olympus HD 3D Laparoscopic Surgical Video System' represents the generic name of the device. This will not be the first use in humans.

This research will take place only at the Cleveland Clinic and will include about 54 people.

You are being asked to participate in this research study because you are scheduled for a laparoscopic total colectomy for ulcerative colitis.

What is involved if you decide to take part in this research study?
If you agree to take part in this study after your questions have been answered, you will be asked to sign this consent form. Your involvement will require just one study visit that will take about 1 hour. The following will occur:

You will be randomized (chosen by chance, like the flip of a coin) to have surgery using either the 2D or 3D visualization. This means that neither the study doctor nor you can choose. The only difference is the video image. The procedure will be performed with the same surgical strategy regardless of the laparoscopy device used.

The study staff will collect the following information from your medical record:

- age, gender, height, weight
- medical history, including the details of your inflammatory bowel disease history
- You will undergo your scheduled standard of care laparoscopic total colectomy. Some details regarding your surgery (such as operating time and the amount of CO2 gas used during surgery) will be collected in the operating room during the procedure
- postoperative outcomes will be recorded

As part of the study, your surgeon will complete a survey after completion of the procedure in order to collect information on his/her experience with the laparoscopy device.

The study staff will place a note in your medical record that states you are participating in this study. The information recorded about you as part of this research will be maintained in a confidential database. Only the study staff will have access to this database.

No extra medications or treatments will be given as part of this research study. You will not be asked to answer a questionnaire, or you will not receive a phone call for research purposes.

The information we will gather from this study is for research purposes only. It is not the purpose of these studies to look for or provide you with any medical information or diagnoses relating to your present condition or any other disease or illness. Therefore, you will not receive results from these research studies.

2. ALTERNATIVES

What are the alternatives to participation in the research study?
You can choose not to participate in this research study. If you do not want to participate in this research, this will not impact your current or future care at the Cleveland Clinic. You will undergo a standard of care laparoscopic total colectomy.

3. RISKS

What are the risks of participating in the research study?

There are rare but serious risks of burns, punctures and surgical complications which are possible during any standard of care approach to 2D or 3D laparoscopic surgery. The only difference is the video image.

Unforeseeable/Unknown Risks:
There may be risks or side effects related to the study drug/device that are unknown at this time. You will be notified of any significant new findings that become known that may affect your willingness to continue in the study.

Confidentiality of Your Data:
Your privacy is very important to us and we will use many safety measures to protect your privacy. There is a potential risk of loss of confidentiality of your data. Information from which you may be personally identified will be maintained in a confidential, locked file at the Cleveland Clinic, and will not be disclosed to third parties except with your permission or as may be required by law. There also may be other privacy risks that we have not foreseen.

4. BENEFITS

What are possible benefits of participating in the research?
There is no personal benefit to you by participating in this research study. Information from this research may be beneficial for other patients, society or science.

5. COSTS

Are there any costs to you if you participate in this study?
There are no additional costs to you for participation in this research study. The cost for routine tests and services that would normally be performed even if you don't participate in the study will be billed to you or your insurance provider. The study related procedures (data collection) will be provided at no cost to you or your insurance company.

6. COMPENSATION

Are there any payments to you if you participate in this study?
You will not be paid for your participation in this study.

7. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?
In the event you are injured as a result of participation in this research, medical care is available to you. The costs of such medical care will be billed to you or your insurance company. There are no plans to provide compensation for lost wages, direct or indirect losses. The Cleveland Clinic will not voluntarily provide compensation for research related injury. You are not waiving any legal rights by signing this form. Further information about research related injury is available by contacting the Institutional Review Board at (216) 444-2924.

8. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may need to see your information for this study. Examples include government groups such as the Food and Drug Administration, safety monitors, and the sponsor of the research (Olympus Corporation) and their agents. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing to Emre Gorgun, MD, Department of Colorectal Surgery, Cleveland Clinic, 9500 Euclid Ave., A30, Cleveland, OH 44195, USA. If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U. S. law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search the Website at any time.

9. CONFLICT OF INTEREST

Do the researchers or institution have any conflicts of interest relating to this study?
The researchers have nothing to disclose.

10. QUESTIONS

Who do you call if you have any questions or problems?
If you have any questions, concerns or complaints about the research, or develop a research-related problem, contact Emre Gorgun, MD at 216-791-6440 during normal business hours. If you need assistance after 5pm, on holiday or weekend, you should contact the page operator at 216-444-2200 or toll free at (800) 223-2273 and ask to page the Colorectal Surgery Fellow on

call. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

11. VOLUNTARY PARTICIPATION

What are your rights as a research participant?
Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled.

12. SIGNATURES

Statement of Participant
I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion
I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date