

Permission to Take Part in a Research Study and HIPAA Authorization for Release of Health Information for Research Purposes

Title of research study: Randomized trial of Intra-Corporeal Anastomosis for RighT colectomies (RICART trial)

Investigator(s): James Ogilvie, Rebecca Hoedema, Arida Siripong, Donald Kim, Martin Luchtefeld

“**You**” refers to the subject.

“**We**” refers to Corewell Health

We invite you to take part in a research study because you are scheduled to undergo a right hemicolectomy via a minimally invasive approach (robotic or laparoscopic) with the creation of an anastomosis.

What are some general things to know about research studies?

- Someone will explain this research study to you.
- You volunteer to be in a research study.
- Whether or not you take part is up to you.
- You can choose not to take part in the research study.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before you decide.

Whom do I call if I have questions or problems?

If you have questions, concerns, or complaints, or think the research has hurt you talk to the investigator or members of the research team at:

Dr. James Ogilvie- james.ogilviejr@corewellhealth.org
Julie Reish julia.reish@corewellhealth.org 616-486-2022

This research has been reviewed and approved by the Corewell Health Institutional Review Board. You may talk to them at (616) 486-2031 or irbassist@corewellhealth.org for any of the following:

- Your questions, concerns, or complaints are not being answered by the investigator or research team.
- You cannot reach the investigator or research team.
- You want to talk to someone besides the investigator or research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Why are we doing this research?

You are being asked to participate in this study because you are scheduled for a minimally invasive surgical procedure (robotic or laparoscopic) to have part of your colon removed, also called a right colectomy. After removing the diseased part of your colon, your doctor will re-connect the healthy parts of your colon (intra-corporeal anastomosis; your colon is re-connected with staples while it remains inside your abdomen or extra-corporeal anastomosis; your colon is re-connected with staples while outside your abdomen). The purpose of this trial is to investigate whether minimally invasive right colectomies (part of the colon is removed) with the intra-corporeal anastomosis technique used result in quicker return of bowel function and earlier discharge.

How long will I be in the research?

We expect that you will be in this research study for approximately 8 weeks after surgery. Your final study visit will also be your regularly-scheduled follow-up visit with your surgeon approximately 8 weeks after your surgery.

How many people will be studied?

We expect about 125 people within Corewell Health will be in this research study.

What happens if I say yes, I want to be in this research?

Your Study Doctor will make sure you are eligible to participate in the study by using a pre-set list of criteria. You will be asked to sign a consent form prior to beginning the research study. You will not give up any legal rights by signing this consent.

The study is a randomized controlled study. Subjects will be randomized to the creation of the anastomosis in either an intra-corporeal or extra-corporeal fashion (intra-corporeal anastomosis; your colon is re-connected with staples while it remains inside your abdomen or extra-corporeal anastomosis; your colon is re-connected with staples while outside of your abdomen). Both techniques are currently being used locally and nationally. The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have a 1 in 2 chance of being given each treatment. This study is a blinded study; which means that only your surgeon and the study coordinator will know if you have been randomized to the creation of the anastomosis in either an intra-corporeal (totally inside the abdomen) or extra-corporeal fashion (partially inside the abdomen). The patients, nursing staff and the perioperative care team (physician assistants,

residents) will be blinded.

If you agree to participate in this study you will be asked about your medical and surgical history, your date of birth, sex, height and weight.

If you choose to be a part of this study, you will need to follow-up in approximately 8 weeks or according to your study doctor's instructions. You must also tell your study doctors immediately if there are any changes in your health while participating in this study. If you choose to stop being part of the study, your study doctor will plan for your continued medical care in accordance with standard clinical practice.

If you have a serious medical problem during the course of the study, please notify your study doctor as soon as possible and he/she will follow-up with you until the problem has resolved, or until he/she feels that it has stabilized, or until all attempts to determine resolution of the problem have been exhausted.

If we learn of new risks that we think might affect your desire to stay in the research we will tell you.

What happens if I say no, I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you. A refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may choose to have your surgery without being part of this study. Instead of being in this research study, your choices may include not participating or participating in another clinical trial, if available. Your doctor will discuss the risks and benefits of these procedures with you.

What happens if I say yes, but I want to stop before my part of the study is complete?

You can agree to take part in the research now and stop at any time. It will not be held against you.

Discontinuing participation will not result in penalty or loss of benefits to which you are otherwise entitled. Your data will not be collected or analyzed under the umbrella of the study.

If you stop being in this research, already collected data may not be removed from the study database.

If you decide to leave the research, contact the investigator.

You will be asked whether the investigator can continue to collect data from your routine medical care. If you agree, this data will be handled the same as research data.

What are the possible risks and discomforts I may have if I take part in this study?

Even though there are lots of risks to surgery, being in the study may make these risks more or less likely to happen.

There are possible risks or discomforts associated with the right colectomy with intra- corporeal and extra-corporeal anastomosis *which may include:*

- Wound infection
- Cardiac complications (stroke, heart attack, rhythm change)
- Lung complications (replacement of breathing tube, transfer to ICU)
- Breakdown of bowel hook-up
- Wound breakdown
- Other infectious complications (urinary tract)
- Blood clot in (lung or elsewhere)
- Prolonged time to bowel function
- Death

In addition to these risks, this research may hurt you in ways that are unknown. There is a risk to you of the possibility of loss of privacy or breach of confidentiality. We are taking steps to minimize this by only allowing Corewell Health Institutional Review Board (IRB) approved study staff to access your chart and enter data into REDCap an electronic database. Your name will be used within the electronic database for the purposes of correlation, but will be stored in a password-protected, institutional provided computers, accessible only to IRB approved study staff. The other inherent risks associated with colectomy surgery will be discussed with you by each operating surgeon. However, this will fall outside the risks of the study itself.

Will I need to pay for any of the tests or procedures in the study?

If your insurance company requires any co-payment or deductible, you will be responsible for making that payment. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If you are confused about what is or is not paid for in this study please discuss this with your study doctor or study staff. There are no experimental procedures being performed as part of this study. The surgery and follow-up procedures as outlined in the procedures section of this informed consent form will be performed as they would normally occur as part of your routine care. The cost of your surgery, any tests associated with your surgery, follow-up visits to your study doctor's office after surgery and any hospital re-admissions will be billed to your health insurer. All costs not covered by your health insurer will be billed to you.

Will being in this study help me in any way?

Although there is a potential benefit with the intra-corporeal anastomosis arm, this has not been proved and therefore there are minimal direct benefits to patients, but it may provide benefits to other patients with the same condition in the future.

How will the information identifying me be kept confidential?

Efforts will be made to limit your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. The following people may inspect and copy your information for quality assurance and data analysis:

- The Investigator and his/her research staff
- The Corewell Health Institutional Review Board (IRB) and its staff
- Public health agencies and other government agencies (including non-U.S.) as authorized or required by law
- Agencies that accredit the hospital or the research program

The above individuals may be given direct access to your medical records for verification of the research procedures/data involved. By signing this document you are authorizing this access.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Federal law provides additional protections of your personal information. These are described in a later section.

Can I be removed from the research without my OK?

The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include: if the participant fails to follow instructions of the research staff, or if the person in charge decides that the research study is no longer in your best interest.

What if I'm Injured or made sick from the research?

No funds have been set aside to pay you in the event of a research related injury.

If you are injured or made sick from taking part in the research study, medical care will be provided.

What else do I need to know?

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

HIPAA Authorization for Release of Health Information for Research Purposes

The information we are asking to use and share is called Protected Health Information (PHI). It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission.

What will be done with my information?

Your health information will be collected and entered into REDCap a database along with the information from other people taking part in this study.

Why am I being asked to release it?

Your health information will be used to potentially help others and benefit the research and medical community. The information we learn from this study may help us to better treat future subjects who need treatment for your condition.

What will be released?

To complete this research study, we will need to collect and release (disclose) information about you. This information may include:

- Your date of birth, name, contact information, medical record number, and insurance information.
- Existing medical records and medical history.
- New health information collected for purposes of this study.

Who will use it or share it?

The people who see your health information for this research study might not be required to follow HIPAA. It is also possible that anyone who receives your health information may re-release it. Because some of these individuals who receive your health information for this study may not be required by law to keep your information confidential, we cannot guarantee that your information will not be released or made available to another party once it leaves Corewell Health. Therefore, we will share your information only if necessary, for the study and we use all reasonable efforts to request that those individuals who receive your information take steps to protect your privacy.

- The investigator and his/her research staff
- The Corewell Health Institutional Review Board (IRB) and its staff
- Public health agencies and other government agencies (including non-U.S.) as authorized or required by law
- Agencies that accredit the hospital or the research program

How long will my health information be used?

This authorization has no expiration date.

Can I stop my protected health information from being collected?

You can tell us to stop collecting health information that can be traced to you at any time. We will stop, except in very limited cases if needed to comply with law, protect your safety, or make sure the research was done properly. If you have any questions about this please ask.

If you want us to stop, you must tell us in writing. If you want us to stop, you must tell us in writing. Write or email:

Dr. James W. Ogilvie
4100 Lake Dr. SE, Suite 205,
Grand Rapids, MI 49546 james.ogilviejr@corewellhealth.org

What happens if I do not want you to collect and release my information?

If you decide not to authorize release of your health information as part of this study, your decision will in no way affect your medical care or cause you to lose any benefits to which you are entitled. You cannot participate in this research study if you do not authorize the use or release of your PHI.

When will it be destroyed?

We do not know when your information will no longer be used. Therefore, the information will be kept for an indefinite length of time.

Documentation of Consent

Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. You will receive a signed copy of this complete form.

Signature of participant

Date

Printed name of participant

Signature of person obtaining consent

Date

Printed name of person obtaining consent