The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title: **Re-Defining Frailty and Improving Outcomes Through Prehabilitation (RIOT Trial)**

Principal Investigator: **Aslam Ejaz, MD**

Sponsor: **The Ohio State University**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

Key Information About This Study

The following is a short summary to help you decide whether or not to be a part of this study. More detailed information is listed later in this form.

This study is looking at a cancer patient's health before surgery, and if simple guided physical exercise before surgery will help to lower your risks and better your healing leading up to and following surgery.

If you participate / if chosen for the exercise group, before surgery you may have your blood drawn, be given simple exercises to do, and have possible follow up phone visits. There will be surveys to complete at appointments or through email after surgery for all that join. There may also be a blood draw the day of surgery, and at your 1st first visit after surgery. We may

also save some tissue samples from the pieces removed by your surgeon. Alternatively, if you participate, but are not chosen for the exercise group, you will still receive standard of care instructions, complete surveys and may have your blood drawn at the same time points, and again have tissues saved. The study lasts about 1 year.

1. Why is this study being done?

In an aging population, a pre-surgical (before surgery) risk check is done to decide if your cancer can be removed. Surgery provides the best hope for long-term survival among patients with abdominal/belly cancers (ex: localized pancreatic, liver, or gastric cancer -where the cancer is only in that organ). However, many of the patients who may have their pancreas, liver, or stomach removed will have problems after surgery. Though chemotherapy after surgery improves cancer-specific survival, many of patients who undergo abdominal cancer surgery will not receive any treatment due to the failure to heal from the surgery or surgery-related problems.

The usual way to check surgical risk is age and current diseases. This is not always accurate. Recently, the idea of frailty has been introduced as a better way to check for risk. Frailty is usually described as weakness related to aging, as well as illness and the ability to handle normal every day stress. Prehabilitation programs, or exercise programs before surgery, try to improve the medical and physical state of patients before surgery. This has not been well studied in people going through cancer surgery.

2. How many people will take part in this study?

144 total (2 groups with 72 in each group)

3. What will happen if I take part in this study?

If you take part in the study, you will be given a study number, simple physical tests (like walking speed/6 minute walk, grip strength, timed up and go “TUG”), a few questions about your daily activities (Katz Index of Independence), feelings (CES-D), memory (mini-Cog), a quality of life questionnaire, as well as a short frailty survey to complete – these are a part of research.

A computer program will randomly, like flipping a coin, select if you will be in the no prehabilitation group or prehabilitation group. Prehabilitation, or prehab, is to help get stronger before an event, like surgery. (See Schedule of Activities on pg 4) The other group will be in the study as a non-prehab group, which means, not doing specific exercises before surgery, but continuing their daily activities as usual.

For those subjects in the non-prehab group, with no assigned exercises, you will receive pre-surgical information from your provider. For those randomized into the prehabilitation group, you will talk with a physical therapist. This is an expert in helping people that have limited

activity or movement in their lives. They will give you low or moderate-high intensity home exercises to work on. These will be done at home during the time before your surgery, but you will have contact with a study team member for any questions. Some people may have trouble completing all the exercises at first, but we are hopeful that the more you try, the more you will be able to finish.

If assigned to the prehab group, the time at home (20-50 mins for 2-3 days/week) before your date for surgery, you will be doing the simple exercises given to you at the physical therapy session, and marking them on the exercise diary provided by physical therapy, in addition to any instructions provided by your care team. This one-time physical therapy session may take about 45 – 60 mins. A research team member will call you each week to check in on your progress and answer any questions you may have about the study. Those in the other group will follow any instructions as given by their care team only.

All enrolled subjects will have their blood drawn. Approximately 30cc or 1 tablespoon of blood may be drawn during your visit 0 (see below). This blood will be processed and stored until the end of the study, here at Ohio State, with your study number on it.

The day of surgery, blood may be drawn when other routine labs are drawn for all enrolled subjects as a part of the study. Also, a very small amount of your tissues, if not needed by pathology, will be taken. This is from the tissues already removed as a part of your surgery.

After surgery, all subjects will be scheduled to follow-up as part of your routine clinic care with your doctor. At this time as a part of this study, you will be asked to complete a quality of life questionnaire, and may have your blood drawn. If you were assigned the prehab group, you ~~will~~ can return the exercise diary on the day of surgery, at one of your post-operative appointments or with the stamped, addressed envelope provided to you.

A study team member will review and collect medical information from all enrolled subjects, for basic information such as height, weight, type of surgery, complications, for example, but subjects will be identified by a study ID number.

Schedule of Activities

	Visit 0	Pre-operative / at home[1]	Phone visit[1](s)	Visit 1 (Day of surgery)	Visit 2 -Week 2 Post-op	Visit 3- Month 3 Post-op	Visit 4- Month 6 Post-op	Visit 5- Month 12 Post-op	End of Study
Informed Consent	X								
Inclusion/exclusion criteria	X								
History and Physical	X								
FRAIL Questionnaire - Randomization	X								
Subject interview / assessments	X								
Physical Therapy consult	X[1]								
Blood collection	X			X	X				
Tissue collection – only what is already being removed from your usual surgery				X					
Exercises		X[1]							
Prehab check-in			X[1]						
PROMIS survey	X				X	X	X	X	X
90-day morbidity assessed via Comprehensive Complicaton Index (CCI)						X			
AE Assessment			X[1]		X	X	X	X	X

1 –only if assigned to exercise
Prehab check-in at Phone visit – Follow-up on exercises, questions, AEs

AE – adverse event
Post-op, post-operative/after surgery
Note: 90-day Morbidity = 3 month review of health status with a trusted guide

If you do not end up having surgery, you will be withdrawn from the study, and will be asked to complete the quality of life suvery (PROMIS).

4. How long will I be in the study?

Approximately 12 months for the entire study, however the exercise program (if you are in that group) will only be during the time between the first session with physical therapy and the day of your surgery. This could be about 2-4 weeks, but may vary depending on the date of your surgery.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

With any exercise therapy program, there are slights risks including pulling or straining muscles, muscle soreness, shortness of breath, muscle tightness in your legs, arms, or abdomen, and in very rare cases dizziness or lightheadedness.

The doctor or study staff will take blood from a blood vessel in your arm by inserting a small needle. Possible side effects of taking blood this way may include tenderness, pain, and bruising at the site where the needle entered the arm, but this will be gone in a few days. Infection, lightheadedness, or fainting is rare.

There is a potential risk to your privacy. Every effort will be made to maintain your privacy, however this cannot be guaranteed.

7. What benefits can I expect from being in the study?

You may or may not benefit from participating in this study. It is possible that exercise therapy, and the education may result in fewer complications following surgery. It is expected that this research will help others in the future.

8. What other choices do I have if I do not take part in the study?

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. What are the costs of taking part in this study?

There is no cost for being in the study.

10. Will I be paid for taking part in this study?

You will not be paid for being in the study.

11. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Wexner Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

12. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

13. Will my de-identified information and bio-specimens be used or shared for future research?

Yes, they may be used or shared with other researchers without your additional informed consent.

14. Will my study-related information be kept confidential?

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups:

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

If we find information that significantly impacts your health, we will share it with you, at your next appointment with your physician.

We will work to make sure that no one sees your survey responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you. Your data will be protected with a code to reduce the risk that other people can view the responses.

15. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about phone calls made as part of this research;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.

- Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information;
- If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician's office record;

IV. Your information may be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

16. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact Aslam Ejaz, MD, MPH at (614) 614-293-7171.

For questions related to your privacy rights under HIPAA or related to this research authorization, please The Ohio State University Medical Center Privacy office at (614) 293-4477.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Aslam Ejaz, MD, MPH at (614) 614-293-7171.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization form**.**

Printed name of participant	**Signature of participant**
	AM/PM
	Date and time
Printed name of person authorized to consent for participant (when applicable)	**Signature of person authorized to consent for participant (when applicable)**
Relationship to the participant	**AM/PM** **Date and time**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	**Signature of witness**
	AM/PM
	Date and time
Printed name of witness	**Signature of witness**
	AM/PM
	Date and time