********************DO NOT DELETE OR ALTER THIS PAGE********************

CAUTION: IF YOU HAVE PRINTED THIS CONSENT FOR USE WITH PARTICIPANTS, IT IS NOT THE IRBMED APPROVED VERSION. Access the approved/watermarked consent from the Documents Tab in the main study workspace. The approved/watermarked document *will not* contain this cover page and *will* have the approval watermark present in the header.

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INSTRUCTIONS FOR EDITING THIS DOCUMENT

1. Turn on Track Changes.
2. Make necessary changes in consent, and update the footer intended for study team version control.
3. Upload the revised consent into Section 10-1, maintaining the IRBMED standard naming convention as follows:
   - **Consent - Tracked**
   - **Consent -** *Concise Subtitle* **– Tracked** (provide a subtitle when there are multiple consents associated with the study)
   - **Assent - Tracked**
   - **Parental Permission/Assent - Tracked**
   - **Parental Permission – Tracked**

NOTES:
Words identified above in bold must not be changed; words identified in italics may be modified by the study team. Informed consent subtitles should be a one or two word descriptor, such as**:** **Consent – *Genetic* – Tracked** or **Consent – *Blood Draw* - Tracked**.

Each subsequent track changes version should be stacked on the previously uploaded track changes version.

DO NOT delete any documents or stacks of documents from eResearch; these are retained for historical and regulatory reference purposes.

DO NOT upload a clean version of the consent**.**

---------- IRB OFFICE USE ONLY ----------

Study ID: HUM00091994 / Continuing Review ID: CR00050323

Approval Date: 10/29/2015

Document Finalized: 10/30/2015 12:20 PM

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title:
Routine post-operative supplemental nutrition: A Randomized Controlled Trial

1.2 Company or agency sponsoring the study:
There is no sponsor for this study.

1.3 Names, degrees, and affiliations of the researchers conducting the study:
Philip W. Carrott, M.D., Department of Surgery, Section of Thoracic Surgery, University of Michigan
Andrew Chang, M.D., Department of Surgery, Section of Thoracic Surgery, University of Michigan
Mark Orringer, M.D., Department of Surgery, Section of Thoracic Surgery, University of Michigan
Jules Lin, M.D., Department of Surgery, Section of Thoracic Surgery, University of Michigan
Rishindra Reddy, M.D., Department of Surgery, Section of Thoracic Surgery, University of Michigan
William Lynch, M.D., Department of Surgery, Section of Thoracic Surgery, University of Michigan

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
The purpose of this study is to determine the best plan of care for post-operative nutritional support following an esophagectomy. Current esophagectomy patients receive tube feeding in the hospital until they can take adequate nutrition by mouth, which is usually 8 days following surgery or until hospital discharge. However, because the amount of food that patients are able to eat varies, some patients may not be able to consistently eat enough to meet their nutritional needs. If a nutritional deficit becomes severe, it can lead to hospital readmission, dehydration and other complications. Continuing tube feeding via jejunal tube for at least 1 month after surgery may decrease the risks of post-operative complications as a result of adequate nutrition and improve patient outcomes following surgery. This research is being done to determine whether continuing tube feeding support for 1 month following surgery is effective in decreasing post-operative complications and improving quality of life and patient satisfaction.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?
Patients who are planning to have an elective esophagectomy with jejunal feeding tube placed at the time of surgery are eligible to take part in this study.

Patients are unable to participate in the study if they:

(1) Have an emergent esophagectomy;
(2) Are less than 18 years of age;
(3) Are unable to provide informed consent or to complete testing or data collection;
(4) Are unwilling to be randomized;
(5) Require tube feeding to continue following hospital discharge (This criteria is assessed prior to randomization).

3.2 How many people (subjects) are expected to take part in this study?

200 subjects will be enrolled into this study. 100 subjects will be randomized to continue tube feeding for 1-month following surgery and 100 subjects will be randomized to receive standard of care (tube feeding to continue in the hospital until patient is able to take adequate nutrition by mouth; which is usually 8 days following surgery or until discharge).

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Before your surgery

On the day of study enrollment, we will collect a pre-surgical quality of life survey and information about scheduled surgery.

After your surgery – During your hospital stay

Following your surgery and while you are in the hospital, we will randomize you to either (1) continue tube feeding support for 1-month following surgery or to (2) usual practice, which is tube feeding to continue in the hospital until able to take adequate nutrition by mouth by post-operative day #8, or upon discharge. Randomization will occur prior to hospital discharge and as soon as you are able to consume food by mouth. If you randomize to continue tube feeding support, we will arrange for tube feeding supplies to be delivered to your home. All esophagectomy patients are discharged with a j-tube port however, if you are randomized to continue tube feeding support, you will be using your j-tube for nutritional support infusion. Nursing homecare support will be available for the duration of the 30-days of continued tube feeding support however, duration and frequency will be dependent upon patient need.

After your surgery – After you are discharged from the hospital

Beginning on the day of discharge, we will ask you to keep a diary of food that you consume each day. A food diary will be provided to you. At your first post-operative clinic visit (usually 2-3 weeks following your surgery), we will collect another quality of life survey and assess for any post-surgical complications and determine your ability to meet your nutritional needs. Following the post-op clinic visit, we will conduct follow-up phone calls at 1-, 3-, and 6-months following surgery to assess for post-operative complications and complete quality of life survey.

4.2 How much of my time will be needed to take part in this study?

Your participation in this study is for six months. After your hospital discharge you will be required to fill out a daily food diary for a period of 1-month. Filing out a food diary will take approximately 1 hour per day. The food diary will be completed at 1-month after your hospital discharge. In addition, you will undergo a brief assessment at 1-month, 3-months and at 6-months after your surgery. These assessments are completed over the phone and will take approximately 10-minutes. You will not need to return to the clinic for the purpose of research after your feeding tube has been removed.

4.3 When will my participation in the study be over?

Your participation in the study will be completed 6 months after your scheduled surgery, however the study team may wish to contact you at a further date to ask you some additional questions. Any coded data you donate to the University databases will be kept there unless you withdraw your participation.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

Discomfort associated with being asked personal questions. It is possible that you may feel discomfort by being asked personal questions about your health history. You may refuse to answer any question on the questionnaires for surveys for any reason.

Confidentiality. There is a risk of the loss of confidentiality about your medical information. We will take all of the following steps to protect your privacy and the confidentiality of your information:

- All data will be maintained in a confidential file with tight security precautions.
- Only researchers involved in this study will have access to information.
- Data will never leave the University of Michigan.

Risks associated with the experimental group:

Increase in the occurrence of tube feeding or jejunal tube complications. Specifically, these risks include diarrhea, j-tube site infection and weight gain. These risks are infrequent (1-10%). These risks are minor but will be minimized by ensuring adequate instruction of patient self-care and care of jejunal tubes. We will routinely monitor patients for signs and symptoms of tube feeding or jejunal tube infection, diarrhea and weight gain.

Risks associated with the standard of care group:

Lack of adequate nutrition. This risk is infrequent (1-10%) and poses moderate risk. The study team will minimize this risk by collecting dietary diets and evaluating patients for signs and symptoms of inadequate nutrition.

Dehydration. This risk is infrequent (1-10%) and poses moderate risk. The study team will minimize this risk by collecting dietary diaries and evaluating patients for signs and symptoms of inadequate nutrition.

Failure to Thrive. This risk is rare but serious. The study team will minimize this risk by routinely assessing patient condition.

Need to restart tube feeding supplements. This risk is infrequent (1-10%) and not serious. The study team will reinitiate tube feeding support if patient condition warrants.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, you may benefit from increased nutritional support in first month following your surgery. Future patients may benefit from the research results, which may ultimately lead to improved ability of doctors to treat future surgical patients.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

Your participation in this study is entirely voluntary. The alternative option is not to participate in the study. Your clinical care will not be affected by your decision to participate in this study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

Participation in this study is completely voluntary. There are no risks involved in leaving the study early. Patients who randomize to the experimental group will need to return tube feeding pump and unused supplies at the time of study termination.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.
- ✓

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. Medical equipment rental will be provided as part of the study however, any cost associated with loss or damage to the rented medical equipment will be the responsibility of the study participant.

If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will not be paid or receive any compensation for participating in this study.

8.3 Who could profit or financially benefit from the study results?

No person or organization has a financial interest in the outcome of this study.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?

Your research information will be stored in a locked cabinet and will not be made a part of your regular medical record. However, if the researcher orders any tests or products (such as tube feeding supplements and supplies), the order may become part of your regular medical record

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Alcohol/substance abuse treatment records
- Billing information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.

- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

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.

9.3 What happens to information about me after the study is over or if I cancel my permission?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:
- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:
- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Philip W. Carrott, Jr., M.D.
Mailing Address:
Department of Surgery
Taubman Center Floor 2 Reception B

1500 E Medical Center Drive. SPC 5344
Ann Arbor, MI 48109
Telephone: 734-763-7337

Study Coordinator: Shari Barnett
Mailing Address:
Department of Surgery
Taubman Center Floor 2 Reception B
1500 E Medical Center Drive. SPC 5344
Ann Arbor, MI 48109
Telephone: 734-936-4561

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.*

12. SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

For use only if required by sponsor:

Date of Birth (mm/dd/yy): _____

ID Number: _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____