Mobile APP Utilization for Enhanced Post-Operative Nutritional Recovery

NCT04091165

ICF Version 1 Dated 6/14/2019

CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY
AND
AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

Study Title:	**"Mobile App Utilization for Enhanced Post-Operative Nutritional Recovery"**
Sponsor:	**Moffitt Cancer Center**
Principal Investigator: (Study Doctor)	**Pamela Hodul, MD**
Telephone: (24 hour number)	**813-745-8459 800-456-3434**
Address:	**Moffitt Cancer Center 12902 Magnolia Drive Tampa, FL 33612**

Doctors and researchers at Moffitt Cancer Center study diseases and other health problems people may have. Our goal is to try to find better ways to help treat these health problems. To do this, we sometimes ask people to take part in research studies.

You are invited to take part in a research study. Research studies only include people who want to take part in the study. Please take the time to read this information carefully. If you have any questions about or do not understand something in this form, you should ask the study doctor or study staff. Discuss your participation with anyone you choose in order to better understand this study and your options. Do not sign and date this form unless the study doctor or study staff has answered your questions and you decide that you want to be part of this study.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information. Being in this study does not replace your regular medical care.

WHAT IS THIS STUDY ABOUT?

You are being asked to take part in this study because you have been diagnosed with gastrointestinal (GI) cancer, and you are scheduled to have surgery to remove the cancer. As part of your care, you will see a dietician for your personalized nutrition plan and goals. We are conducting a pilot study to determine if a digital food diary, called *MyPlate Calorie Counter*, can be used in the clinical setting, as part of the management of GI cancers, to help you meet your nutritional goals. We believe that including this mobile app with your cancer management may

help keep you on-track with your post-surgery dietary recommendations and improve the quality of your recovery.

Digital Food Diary: *MyPlate Calorie Counter* (a smartphone application)

MyPlate Calorie Counter (https://www.livestrong.com/myplate/) is a free, user-friendly weight management smartphone application. The application behaves as a digital food diary available for smart phone devices, recording your daily caloric entake and provides in-depth analytics on your eating habits. Users have the option to input items manually (for example, calories, carbohydrates, fats, and proteins), select from a list of popular food items, or scan barcodes on the food packaging. In addition to food entries, users can also enter daily water intake and physical activities. Once an account is created, data entered into the mobile application can be sync'd to the *MyPlate Calorie Counter* website.

PURPOSE OF THE STUDY

The purpose of this pilot study is to assess the usability and acceptability of maintaining a digital food consumption diary as part of the management of participants with GI cancers and to evaluate the impact of a digital food diary (*MyPlate Calorie Counter*) on adherence to dietician-recommended plan and on quality of recovery.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

About 20 participants will take part in this study at Moffitt Cancer Center.

WHAT WILL HAPPEN DURING THIS STUDY?

Before you can start the study, the study doctor or study staff will talk to you about the study. We will also ask you a couple of questions regarding your mobile phone capabilities. You have to sign and date this form before the study doctor or study staff can begin study procedures.

Study participation includes completing surveys with members of the research team and entering your eating habits, physical activity and water intake at your leisure. It also includes things that you will give us permission to complete. This includes reviewing your medical records and your food diary entries on *MyPlate Calorie Counter* (accessed from the website).

Seeing a dietician before and after surgery is part of your routine care at Moffitt Cancer Center. Study procedures will occur during your appointments with a dietician at Moffitt Cancer Center. You will be scheduled to see a dietician once before your surgery and 3 times after your scheduled surgery. The section below (**WHAT HAPPENS WHEN I COME FOR STUDY VISITS**) will describe in detail the study procedures that you will go through.

Using *MyPlate Calorie Counter*

Once you sign and date this form, you agree to use the smartphone application, *MyPlate Calorie Counter* to track your daily food/water intake and physical activity. During your first visit with the dietician (**Study Visit 1**), you will be asked to download the smartphone app, *MyPlate Calorie Counter*. This app is free to download, but data usage charges may apply and will be your responsibility. The dietician will provide a tutorial of the application, answer any of your questions and troubleshoot, if necessary. After the tutorial, the dietician will provide a username and password and create a study account for you. During **Study Visit 2** (details below), the dietician will enter your nutrition plan and recommendations into your *MyPlate Calorie Counter*

account. Using *MyPlate Calorie*, you will start tracking your daily eating/drinking habits and physical activity after you have been discharged from the hospital (post-surgery).

For the duration of the study, the research team will have access to your account and will be able to view your entries (for research purposes only). At each study visit, the research team will extract data recorded in your *MyPlate Calorie Counter* acount into a password-protected file. Once you have completed the study, a member of the research team will assist with changing your password so that you can continue to use *MyPlate Calorie Counter* for personal use. Or, if you choose to not continue to use the application, a member of the research team will assist with deleting your account with *MyPlate Calorie Counter*. Therefore, at the completion of the study, the study doctor and research team can no longer access your *MyPlate Calorie Counter* account.

WHAT HAPPENS WHEN I COME FOR STUDY VISITS?

After you sign and date this form, the study doctor or study staff will do the things listed below when you come in for study visits. If you would like more information about which procedures will be done at each study visit, ask the study doctor or study staff.

Study Visit 1

Your first study visit with a dietician will be 2 weeks (14 days) before your scheduled surgery date. At this time, you will download *MyPlate Calorie Counter* onto your smartphone. The dietician will show how to use the app, *MyPlate Calorie Counter*, and answer any questions you may have. The dietician will also set up your account and give you the login information (username and password) on a reminder card. As a reminder, the research team will have access to your account for research purposes only.

Study Visits 2, 3 and 4 will occur after your planned surgical procedure

Study Visit 2

Study Visit 2 will occur during a routine visit with the dietician, while you are in the hospital recovering from surgery. The dietician will explain in detail your nutritional plans and goals post-surgery, which may include recommended calorie, fat, carbohydrate and protein consumption. The following will also occur during this visit:

- Dietician will enter your personalized plan into your *MyPlate Calorie Counter* account and provide instructions on how to record your daily intake of food/water and physical activity.
- Perform a routine physical examination
- Administe a survey about your recovery

You can start recording your daily food/water intake and physical activity as soon as you are discharged from the hospital.

Study Visit 3

You will be scheduled to see the dietician 2 weeks (14 days) after your hospital discharge date. During this visit, the dietician and a member of the research team will complete the following procedures:

- Perform routine physical examination
- Administer a survey about your recovery

- Review your progress and daily entries recorded by the mobile application.
- Depending on your progress, the dietician may make adjustments to your personalized nutrition plan.
- Extract your *MyPlate Calorie Counter* data
- You will be instructed to continue your daily entries into the application.

Study Visit 4 – Final Visit

The final study visit will correspond with your scheduled appointment with the dietician 6-8 weeks after your hospital discharge date. During this visit, the dietician and a member of the research team will complete the following procedures:

- Perform routine physical examination
- Administer surveys about your recovery and your experience with using *MyPlate Calorie Counter*
- Review your progress and daily entries recorded by the mobile application.
- Depending on your progress, the dietician may make adjustments to your personalized nutrition plan.
- Extract your *MyPlate Calorie Counter* data
- Assist with changing your password so that you can continue to use *MyPlate Calorie Counter* for personal use.

WHILE YOU ARE IN THE STUDY, YOU MUST:

- Follow the instructions you are given.
- Use MyPlate Calorie Counter to track your daily intake and activities
- Come to Moffitt Cancer Center for all visits with the study doctor/dietician.
- Give correct and accurate information
- Tell the study doctor about any health problems you have during the study.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

HOW LONG WILL I BE ASKED TO STAY IN THIS STUDY?

You will be asked to spend a total of 2 months in this study.

WHAT ARE MY ALTERNATIVES TO BEING IN THIS STUDY?

You do not have to be in this study to treat your GI cancer. The study doctor will talk to you about other things you can do for your condition, including their important risks and benefits. Your participation in this study is voluntary. You can decide not to be in the study and you can change your mind about being in the study at any time. There will be no penalty to you, and you won't lose any benefits. Your regular medical care at this study center will not change if you decide not to be in the study. Some other things you may be able to do are:

- Care for your condition without being in a study
- Take part in another study
- Receive no treatment with care to support you and treat symptoms – called palliative care or "comfort care." This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and

comfortable as possible. If you think you might prefer comfort care, please discuss this with your family, friends and your doctor.

Talk to your study doctor about your choices and those risks and benefits of the choices before you decide if you will take part in this study.

WHO IS PAYING FOR THIS STUDY?

Moffitt Cancer Center is paying for this study.

WILL IT COST ANYTHING TO BE IN THIS STUDY?

You and/or your insurance company will be financially responsible for hospital inpatient, outpatient and follow-up visits that would normally or routinely occur in the management of your disease. Inpatient and outpatient visits could include charges for treatments, medications, physician visits, laboratory tests and procedures. You and/or your insurance company will be responsible for paying for the charges which are considered routine, since you would have received these services even if you were not participating in this study. You will be responsible for any costs not covered by your insurance company, including deductibles, co-payments and all out-of-pocket expenses. Before you agree to be in this study, you should contact your health insurer to see if your plan will cover the costs required as part of your participation.

You and/or your insurance company will not be responsible for paying for study-related items and services that are specifically required for this research study and are not considered part of the routine management of your disease, if these procedures are performed at Moffitt Cancer Center.

Although the application is available at no charge, data usage charges may apply (depending on your mobile carrier) and will be your responsibility.

If you would like more information on the costs of being on this study or have other insurance related questions, please let your clinical trial coordinator know or contact our Business Office at 813-745-8422.

POTENTIAL BENEFITS: WILL BEING IN THIS STUDY HELP ME?

The use of the mobile application, *MyPlate Calorie Counter* may help treat your GI cancer condition by monitoring your nutritional intake after surgery, but there is no guarantee that being in this study will help you. Future patients with your condition may benefit from what is learned from this study.

POTENTIAL RISKS: ARE THERE RISKS TO ME IF I AM IN THIS STUDY?

The potential risks or discomforts for participants included in the study are minimal. No new procedures or changes in routine care and treatment will occur during this study. There is a potential risk for the loss of confidentiality for all study participants; however, every precaution will be taken to ensure all identifiable data collected as part of the study is kept confidential (details below).

Procedures to Maintain Confidentiality

The risk for loss of confidentiality will be minimized by the following procedures. Identifiable information (name, MRN) will be used only during initial data collection (for example, medical

chart review), after which a unique numerical identifier (for example, study ID) will be assigned for each participant and the identifiable information will no longer be used or included in the main database. Collected data will be maintained on a password-protected excel datasheet and/or Access database at Moffitt Cancer Center, maintained by the research study team in the Department of Gastrointestinal Oncology. Only the research team will have access to collected data and the completed dataset. All study files will be password-protected.

IF I STOP TAKING MY REGULAR MEDICATION, WHAT ARE THE RISKS?

If you stop your regular medication to be in the study, your GI cancer might come back or get worse. Please tell the study doctor or study staff right away if you have any problems when you stop taking your regular medications.

WHAT IF I GET HURT OR SICK WHILE I AM IN THIS STUDY?

If you need emergency care:

- Call 911 or go to your nearest emergency room right away. Moffitt Cancer Center does not have an emergency room or the facilities to provide emergency care.

If you do NOT need emergency care:

- Call or go to your regular doctor. It is important that you tell your regular doctor that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

If you experience a side effect or a change in the way that you feel, call the study doctor at the telephone number listed on the first page of this form.

By signing this informed consent and research authorization form, you have not given up any legal rights to seek compensation for injuries from the sponsor**.**

MOFFITT CANCER CENTER INJURY STATEMENT

If you believe you have been injured as a result of your participation in this study or if you have questions about your rights as a person who is taking part in a research study, you may call the Moffitt Cancer Center Risk Manager at 813-745-4219. Moffitt Cancer Center and its investigators have made no provision for monetary compensation in the event of physical illness or injury resulting from this study. Likewise, Moffitt Cancer Center and its investigators have made no provision for payment of lost wages, disability, or discomfort in the event of physical illness or injury resulting from this study. Florida law (Statute 768.28) limits the liability of Moffitt Cancer Center. This statute provides that damages are available only to the extent that negligent conduct of a Moffitt Cancer Center employee caused your injuries, and are limited by law.

WILL I GET PAID?

You will not be paid for being in this study.

The findings from this research may result in the future development of products or patents that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

DO I HAVE TO BE IN THIS STUDY?

You can decide whether to take part in this study or not. Participation is voluntary. You are free to say yes or no. If you say no, your regular medical care will not change, and there will not be any penalty or loss of benefits to which you are entitled. Even if you join this study, you do not have to stay in it. You may stop at any time and your regular medical will not change. You do not need to provide a reason to stop.

DO I HAVE TO REMAIN ON THIS STUDY ONCE I JOIN?

If you want to stop being in the study, tell the study doctor or study staff. If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. To help you leave the study safely, the study doctor may ask you to participate in more tests or return for a final study visit.

ARE THERE REASONS THE STUDY DOCTOR MIGHT TAKE ME OUT OF THE STUDY LATER?

Even if you want to stay in the study, there may be reasons the study doctor or study staff will need to take you out of it. Your study doctor has the right to take you out of the study at any time with or without your agreement. Your participation may be ended without your consent for different reasons, including the following:

- If the study doctor believes, for any reason, that it is in your best interest.
- If you develop side effects that the study doctor considers unacceptable.
- If you refuse to use the mobile application (digital food diary – *MyPlate Calorie Counter*) or return for follow-up as recommended by your study doctor, or do not follow the study doctor's instructions.
- If you require treatment with drugs that are not allowed on this study.
- If other causes prevent you from continuing in this study.
- If the study doctor decides to end the study.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment and because of federal law, we must obtain your written authorization before we use or disclose your information for this study.

By signing this form, you are permitting researchers at Moffitt Cancer Center to use personal health information for research purposes within its organized health care arrangements. You are also allowing the Moffitt Cancer Center to disclose your personal health information to outside organizations or individuals that participate in this study. We may publish what we find out from this study. If we do, we will not let anyone know your name. We will not publish anything that would directly let people know who you are.

WHO WILL DISCLOSE, RECEIVE, AND/OR USE YOUR INFORMATION?

Your records are confidential and they will be kept in a secure environment and protected to the full extent of the law.

To do this research, the following people and/or organization(s) will be allowed to disclose, use, and receive your information, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law:

- Every research site for this study, including the Moffitt Cancer Center, and each site's study team, research staff and medical staff.
- Any person who provides services or oversight responsibilities in connection with this study.
- Every member of the Moffitt Cancer Center workforce who provides services in connection with this study.
- The person who is responsible for the study nationwide or worldwide (study chairperson).
- Any laboratories, individuals, and organizations that use your health information in connection with this study.
- Any federal, state, or local governmental agency that regulates the study (such as the U.S. Food and Drug Administration (FDA) and Florida Department of Health (FDH). The U.S. Department of Health & Human Services (DHHS), Office for Human Research Protections (OHRP).
- Other government agencies in this or other countries.
- The designated Protocol Review and Monitoring Committees, Institutional Review Boards such as Advarra IRB, Privacy Boards, Data and Safety Monitoring Board and their related staff that have oversight responsibilities for this study.
- The National Cancer Institute in evaluating the ongoing research of the Moffitt Cancer Center as a Comprehensive Cancer Center.

The organizations and people listed above may employ or pay various consultants and companies to help them understand, analyze and conduct this study. All of these people may not be known now, but if you would like to have more specific information about this at any time during the study, you may ask the study doctor and your questions will be answered.

Moffitt Cancer Center cannot guarantee the privacy of your information, or block further use or distribution, after the information has left the Moffitt Cancer Center. Others listed above may further disclose your information, and it may no longer be covered by federal privacy regulations. If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes. You might have the right to see and copy your health records related to this research. You might not be able to see or copy some of your records until after all participants finish the study. If it is necessary for your care, your records will be provided to you or your regular doctor.

WHAT INFORMATION WILL BE USED OR DISCLOSED?

By signing below, you authorize the use and disclosure of your entire study record and any medical or other records held by Moffitt Cancer Center, including, but not limited to, HIV/AIDS, mental health, substance abuse or genetic information. The purpose for the uses and disclosures you are authorizing is to conduct the study explained to you during the informed consent and research authorization process and to ensure that the information relating to that study is available to all parties who may need it for research purposes.

Your authorization to use your health information will never expire unless and until you expressly revoke it in writing to the study doctor listed on the first page of this form. Any data collected before your letter will continue to be used as necessary to preserve the integrity of the study, however no additional information will be collected after you withdraw your authorization.

You will receive a signed and dated copy of this form.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document. If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail:
  Study Participant Adviser
  Advarra IRB
  6940 Columbia Gateway Drive, Suite 110
  Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Participant Adviser: Pro00033547.

WHERE CAN I GET MORE INFORMATION?

You may call the National Cancer Institute's (NCI) Information Service at:

1-800-4-CANCER (1-800-422-6237).

Visit the NCI's Websites at:

- CancerTrials: comprehensive clinical trial information at: http://cancertrials.nci.nih.gov
- CancerNet: accurate cancer information including PDQ at: http://cancernet.nci.nih.gov

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.

STATEMENT OF CONSENT

I have read this form and its contents were explained to me. I agree to be in this research study for the purposes listed above. All of my questions were answered to my satisfaction. I will receive a signed and dated copy of this form for my records.

_____
Printed Name of Participant

_____ _____ _____
Signature of Participant Date Time

STATEMENT OF PERSON OBTAINING INFORMED CONSENT/RESEARCH AUTHORIZATION

I attest that the participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____
Printed Name of Person Explaining Consent

_____ _____ _____
Signature of Person Explaining Consent Date Time