DEPARTMENT OF SURGERY
Division of Cancer Control
URCC NCORP Research Base
WCI Cancer Control and Survivorship Research Program

UNIVERSITY of ROCHESTER MEDICAL CENTER

CONSENT FORM

The Diet and Nutrition in Cancer (DANICA) study:
The effects of a Mediterranean Diet on preventing cancer-related fatigue during chemotherapy
clinicaltrials.gov identifier: NCT04534738

Principal Investigator: Amber S. Kleckner, PhD

This consent form describes a research study, what you may expect if you decide to take part, and important information to help you make your decision. Please read this form carefully and ask questions if anything is not clear before you agree to participate.

Key Information

Most patients with cancer experience tiredness during treatment, referred to as "cancer-related fatigue." However, there are currently no adequate treatments. This study has three main goals: 1) to assess what patients like to eat (and not eat) while undergoing chemotherapy, 2) to assess the feasibility of beginning a Mediterranean Diet plan during chemotherapy, and 3) to assess the effects of diet on the development and progression of fatigue.

- Being in this research study is voluntary—it is your choice. Participation in this study will not affect your treatment for your cancer in any way.
- You are being asked to take part in this study because you have been diagnosed with cancer, you are scheduled to receive chemotherapy and have at least 6 weeks remaining, and you are not currently following a Mediterranean Diet but have no dietary restrictions that will prevent you from following a Mediterranean Diet plan.
- Your participation in this study will last for about 2 months.
- Procedures will include answering questionnaires about your symptoms, feelings, and eating habits as well as three blood draws. Some of these procedures may be optional. You will be randomly assigned to the Mediterranean Diet group or the usual care group (there is a two-thirds (67%) chance you will be assigned to the Mediterranean Diet group). Those in the Mediterranean Diet group will be asked to follow the Mediterranean Diet plan for 8 weeks; we will provide food for 4 of those weeks (more information below).
- There are risks from participating.
    - One of the most serious risks is an allergic reaction to a food. See the "Risks of Participation" section in this consent form for more information. You should discuss these risks in detail with the study team.
- You will likely not benefit from being in this study. However, a potential benefit to you might be that you become more aware of the foods you eat and you might be able to add new, healthy recipes to your routine.

Purpose of Study

Patients and clinical care teams intuitively understand the importance of nutrition in being healthy. However, we don't know how diet during chemotherapy affects the development of cancer-related fatigue. The purpose of this study is to see if people can adopt the Mediterranean Diet plan during chemotherapy, and to test the effects of a Mediterranean Diet plan vs. typical dietary choices during chemotherapy on the development of fatigue.

Description of Study Procedures

If you decide to take part in this study, you will be asked to participate in the following study activities. It is expected that how you feel will change over the course of your chemotherapy treatment, and we would like to see how diet affects these changes. More information regarding each of the activities is provided below.

At the beginning of the study (baseline):

- Complete questionnaires regarding your symptoms, feelings, and normal diet.
- Complete a 3-day food log.
- Provide a blood sample (approximately 3 tablespoons of blood).

Throughout the study (8 weeks):

- If you are in the Mediterranean Diet group, we will give you information on the Mediterranean Diet, including its principles and components, and help you follow it. We will provide Mediterranean Diet meals for 4 weeks.
- Record your fatigue level every day on a daily diary.

At 4 weeks (mid-point):

- Complete questionnaires regarding your symptoms, feelings, and diet.
- Complete a 3-day food log.
- Provide a blood sample (approximately 3 tablespoons of blood).

At 8 weeks (the end of the study):

- Complete questionnaires regarding your symptoms, feelings, and diet.
- Complete a 3-day food log.
- Provide a blood sample (approximately 1.5 tablespoons of blood).
- Participate in an exit interview, telling us what you thought about the study.
- Those in the usual care group will be provided with the intervention materials and one week of the Mediterranean Diet food.

Questionnaires

We will ask you to complete 10 questionnaires that will take approximately 30-45 min to complete. The questionnaires will ask you about your symptoms, feelings, and normal diet, as well as provide us with other relevant information. One of the questionnaires is a 3-day food record that includes everything you eat for 3 days. Many of these questionnaires can be completed online, and they do not have to be completed in one sitting. Alternatively, you can complete paper-based versions.

Blood draw
We will collect approximately 3 tablespoons of blood at the beginning of the study (week 0) and at the 4-week mid-point, and then approximately 1.5 tablespoons at 8 weeks. These collections will be taken in conjunction with your regularly scheduled blood draws (e.g., before your chemotherapy infusion), if possible. This blood will be used to measure features of your metabolism.

Randomization
You will be randomly assigned to either the Mediterranean Diet group or the usual care group. This means that your group assignment will be completely by chance, like pulling a number out of a hat. You have a two-thirds chance of being assigned to the Mediterranean Diet group (67% chance).

Mediterranean Diet
If you are assigned to the Mediterranean Diet intervention, you will be encouraged to follow a Mediterranean Diet plan for 8 weeks. The Mediterranean Diet is high in fruits, vegetables, whole grains, nuts, and olive oil, and is low in sugar and processed food. It has been shown to improve heart health, though it has not been tested during chemotherapy to prevent fatigue. We will give you instructions on what the Mediterranean Diet is, specifically what foods are encouraged and what foods are discouraged. Meals will be delivered to your house from Project Lean Nation and will be provided for 4 weeks to help you follow the diet, though eating the provided food is not required. Wegmans Instacart (or an alternative based on availability in your area) will also deliver other ingredients and food to your house to help you cook within a Mediterranean Diet. You may supplement and/or substitute other foods of your choosing.

Usual care group
If you are assigned to the usual care group, you are encouraged to make no conscious changes to your diet. The information from the usual care group is extremely valuable in that we can get a clearer picture of what patients prefer to eat during the chemotherapy experience, and if dietary preferences correlate with symptoms you may be experiencing. At the end of the study, you will be offered information on the Mediterranean Diet and one week of Mediterranean meals from Project Lean Nation and Wegmans Instacart (or a local alternative).

Contact during the study
We will be in contact with you throughout the study period via phone, email, and/or text message based on your personal preference. We will check in with you weekly to see how the study is going and to remind you of upcoming appointments.

Exit-interview
At the end of the study, we will "interview" you regarding your participation in the study: what you liked, what you didn't like, etc. You have the option of having your exit-interview audio-taped for research purposes. The recording may be used to make a transcription of your interview (i.e., we will type up the conversation). Your name will not be included in the transcription.

Number of subjects
Approximately 42 subjects from Wilmot Cancer Institute and affiliated sites (e.g., Pluta Cancer Center) will take part in this study.

Risks of participation

As with all research studies, there are risks associated with the study activities. We have taken measures to minimize all anticipated risks. Please consider these risks while deciding if you want to participate.

1. *Weight loss due to adoption of the Mediterranean Diet*
   This is not a weight loss study. Some studies have documented weight loss upon adoption of the Mediterranean Diet despite not purposefully "cutting calories." We encourage all subjects to eat and drink to satisfy hunger and thirst. However, because many of the foods in the Mediterranean Diet are very filling, and the fact that you are being treated for cancer with chemotherapy, there is a chance that you could lose weight during the study. Slow weight loss will not be considered dangerous (less than approximately 4 pounds or 2 kg per week), especially if you are beginning the study overweight. However, if you experience rapid, unintentional weight loss, as monitored and determined by your oncologist, he or she will advise you on what to do, which may involve withdrawing from the study.

2. *Gastrointestinal upset*
   With a change in diet, and especially a large change in diet, you could experience constipation, diarrhea, nausea, heartburn, bloating, or flatulence. These effects usually go away after several days, but you will always has access to the study chair, Dr. Kleckner, as well as a dietitian to discuss how to relieve these effects.

3. *Emotional distress*
   If you are assigned to the Mediterranean Diet group, you could become emotionally distressed or overwhelmed by the expectation to consume the food provided to you. However, you are not limited to these foods, and you do not have to eat them. We are providing the food only to help you follow the Mediterranean Diet for our study. We encourage you to cook, eat out with friends and family, etc.

   Our questionnaires contain information that might be distressing or private (e.g., "I am satisfied with family communication about my illness"). You do not have to answer any questions you are not comfortable answering, and you can take a break or stop answering the questionnaires at any time.

4. *Risks from a blood draw*
   Bruising, bleeding, and pain could occur where the blood samples are taken. Sometimes, drawing blood causes people to feel lightheaded or even faint. To avoid these risks, all blood will be drawn at the Wilmot Cancer Institute or UR-affiliated labs by trained staff and we will use a port if you have one. Specifically, to minimize the chance of bruising and the slight chance of infection associated with blood collection, the labs employ standardized hospital procedures for blood collection, and use a trained phlebotomist and sterile materials. You will be encouraged to be well-hydrated before and after the blood draw, and to consume food soon after the blood draw.

5. *Breach of confidentiality*
   There is always a risk of a breach of confidentiality in which sensitive medical information could become known to persons outside the research team. To avoid leakage of sensitive information, only Dr. Kleckner (the study chair), Ms. Jennifer Reschke (the study coordinator), and any individual

designees will have access to the screening log and the file that links your name with your subject number (both will be encrypted); these files will be stored on a password-protected computer in Dr. Kleckner's private office. All data files will reference you by a non-identifiable Participant ID and will be stored on Dr. Kleckner's computer and secure servers at URMC. All consent forms will be stored in a locked cabinet also in her office. If Dr. Kleckner shares data with any other researcher for analyses, all data will be deidentified (i.e., will not have name, birthdate, contact information, etc.). Presentation of study findings in the form of posters, presentations, and manuscripts, either in private or public settings, will not have any identifiable information. Dr. Kleckner and all other co-investigators participate in ethical training in accordance with institutional policies.

We will share your name, address, and phone number with Project Lean Nation as well as Wegmans Instacart (or local alternative) so that they can deliver meals and other food items to your house. There is a possibility of you receiving mailing advertisements from these companies after your study participation is over. You may opt out of these mailings by contacting these companies directly. No health information will be shared with these companies.

Alternatives to participation
You may seek other nutritional services in addition to or instead of participating in this study regardless of your group assignment. You may choose to not participate in the study without penalty or effects on subsequent medical care.

Benefits of participation
You may or may not directly benefit from this study. You will be provided with healthy Mediterranean Diet meals for 4 weeks (if you are assigned to the Mediterranean Diet group) or 1 week (if you are assigned to the usual care group). It is our hope that providing this food will help reduce the burden of meal planning, grocery shopping, and cooking.

Costs
There will be no cost to you to participate in this study.

Payments
You will receive $20 for completing the study. You will not be reimbursed for any food you purchase.

Payment received for participation in research is considered taxable income. If you receive payment for your participation in studies at the University of Rochester and its affiliates of $600 or more in any one calendar year, the University is required to report this information to the Internal Revenue Service (IRS) in a 1099 (Miscellaneous Income) form. You will be sent a copy of this form and a copy will be sent to the IRS. Depending on the amount you are paid, you may be asked to submit a W-9 form, which includes your Social Security Number.

Voluntary Participation
Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

If you are a student at University of Rochester or URMC, participation will not affect your class standing or grades. You will not be offered or receive any special consideration if you take part in this research.

If you are an employee at University of Rochester, URMC, or its affiliates, taking part in this research is not a part of your duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

Withdrawing from the study

Early Termination: If you decide to withdraw from the study, you will not experience any negative consequences (e.g., to your cancer treatment or care).

Circumstances for Dismissal: You may be withdrawn from the study if your disease becomes worse or if your doctor feels that staying in the study is harmful to your health. The study team also holds the discretion to withdraw you from the study if your participation becomes harmful to yourself or others.

New Study Information: If we discover any new information that might make you change your mind about continuing in the study, we will relay the information.

Your medical record

As part of this study we will collect some information from your medical record. This will include information such as your age, sex, race, cancer diagnosis, medications you are taking, and the results of any laboratory or diagnostic tests.

Information about your study participation and study results may be included in your electronic health record. If you have concerns about this or to obtain more detail, you should discuss this with the study team.

The study team may be notified if you receive other health care services at University of Rochester Medical Center (URMC) or its affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of testing conducted for this study:

- Staff at the UMRC and its affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Healthcare providers who are involved in your care at a facility that is not part of the URMC and its affiliates and who have reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

Confidentiality of records and authorization to use and disclose information for research purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, access to study files is restricted only to study personnel who need access. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators, or the study sponsor. However, if any personal information needs to be shared for these purposes, it will not be made public.

If you have never received a copy of the URMC and affiliates' Notice of Privacy Practices, please ask the investigator for one.

- *What information may be used and given to others?*
  The study chair will hold your personal and medical information. For example:
  - Research records
  - Records about phone calls and emails made as part of this research
  - Records about your study visits
  - Past and present medical records related to the study, including records of external providers that are available via your electronic health record at URMC & affiliates
  - Results of medical tests (e.g., pregnancy test)

- *Who may use and give out information about you?*
  - The study chair and the study staff
  - URMC and affiliates

- *Your information may be given to:*
  - The Department of Health and Human Services
  - The University of Rochester
  - The National Institutes of Health, who sponsor this research
- *Why will this information be used and/or given to others?*
  - To do the research
  - To study the results
  - To see if the research was done correctly
  - If the results of this study are made public, information that identifies you will not be used.

- *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.

- *May I review or copy my information?*
  Yes, but only after the research is over.

- *How long will this permission be valid?*
  This permission will last indefinitely. As per policy, all records and databases will be maintained for at least 6 years after the study is complete.

- *May I cancel my permission to use and disclose information?*
  Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study chair. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

- *May I withdraw from the study?*
  Yes. If you withdraw your permission to be in the study, 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.

- *Is my health information protected after it has been given to others?*
  No. There is a risk that your information will be given to others without your permission.

Certificate of Confidentiality
To help us further protect your privacy, the investigators have a Certificate of Confidentiality from the Department of Health and Human Services (DHHS).

With this Certificate, the investigators cannot be forced (for example, by court subpoena) to disclose or use research information, documents, or samples that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, other proceedings, or be used as evidence. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes, or to other government agencies related to communicable diseases.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your consent to receive research information, then the investigator may not use the Certificate to withhold that information. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Future Use of Blood Samples
Your blood samples might be used for future research studies without additional informed consent. All identifiers will be removed before your samples are used. You will be given the option at the end of this consent form to decide if you would like your samples used for future research.

Public description of this study
A description of this clinical trial is available on http://www.ClinicalTrials.gov, as required by U.S. law (ClinicalTrials.gov identifier: NCT04534738) This website will not include information that can identify you. The website includes a general description of the study (e.g., population, outcomes, status), and will eventually include a summary of the results. You can search this website at any time.

Sponsor Support
The University of Rochester is receiving payment from the National Cancer Institute for conducting this research study (NIH/NCI T32 CA102618, NIH/NCI UG1 CA189961).

Commercial Profit
We will use your information and blood samples for research only. However, the results of this research might someday lead to the development of products (such as a commercial diet or product) that could be sold by a company. You will not receive money from the sale of any such product.

Return of Research Results
In general, we will not give you any individual results from your participation in the study. If we find something of urgent medical importance to you, we will inform your oncologist, although we expect that this

will be a very rare occurrence. Once the study is completed, we will post the results (e.g., averages of all subjects) on our lab's website:
www.urmc.rochester.edu/people/31323710-amber-s-kleckner

Contact Persons

If you have any questions about this study and you would like to reach the study team, please contact the study chair:

Amber Kleckner, PhD
work: (585) 276-3440
cell: (585) 371-7898
amber_kleckner@urmc.rochester.edu

For more information concerning this research or if you feel that your participation has resulted in any research-related injury, emotional or physical discomfort, please contact the study's medical monitor:

Allison Magnuson, DO
(585) 487-1700

If you wish to talk to someone other than the research staff about your rights as a research subject; to voice concerns about the research; to provide input concerning the research process; or in the event the study staff could not be reached, please contact:

The University of Rochester Research Subjects Review Board
265 Crittenden Blvd., CU 420628
Rochester, NY 14642
(585) 276-0005 or (877) 449-4441

Use of Email for Communication in Research

When using email to communicate with you in this study, the researcher cannot guarantee, but will use reasonable means, to maintain security and confidentiality of email information sent and received. You and the researcher should understand the following conditions, instructions and risks of email use:

Conditions for email use:

a) Email is not appropriate for urgent or emergency situations. The researcher cannot guarantee that any particular email will be read and responded to.
b) Email must be concise. You should schedule an appointment if the issue is too complex or sensitive to discuss via email.
c) Email communications between you and the researcher will be filed in your research record.
d) Your messages may also be delegated to any member of the study team for response.
e) The researcher will not forward subject-identifiable emails outside of URMC and Affiliates without your prior written consent, except as authorized or required by law.
f) You should not use email for communication regarding sensitive medical information.
g) It is your responsibility to follow up and/or schedule an appointment if warranted.

Instructions for email use:

a) Avoid use of your employer's computer.
b) Put your name in the body of the email.
c) Put the topic (e.g., study question) in the subject line.
d) Inform the researcher of changes in your email address.
e) Take precautions to preserve the confidentiality of email.
f) Contact the researcher's office via conventional communication methods (phone, fax, etc.) if you do not receive a reply within a reasonable period of time.

Risks of email use:

Sending your information by email has a number of risks that you should consider. These include, but are not limited to, the following:

a) Email can be circulated, forwarded, stored electronically and on paper, and broadcast to unintended recipients.
b) Email senders can easily misaddress an email.
c) Backup copies of email may exist even after the sender or the recipient has deleted his or her copy.
d) Employers and on-line services have a right to inspect email transmitted through their systems.
e) Email can be intercepted, altered, forwarded, or used without authorization or detection.
f) Email can be used to introduce viruses into computer systems.

Use of Text Message Communication for Research

Text messages by mobile/cell phones are a common form of communication. This study involves sending you text messages about scheduling and reminders of your study visits. You can also text Dr. Kleckner if you have any questions about the study. Dr. Kleckner uses Google Voice to correspond with participants via text

message. Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This research study and the University of Rochester are not responsible for any interception of messages sent through unencrypted text message communications.
- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and the University of Rochester are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.
- Text messages will only be read during regular business hours. Texts sent on nights, weekends, and holidays will not be read until the following business day.
- Text messaging should not be used for sensitive medical information, or in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says "Stop Research Text."
- Your agreement, and any request to stop text messaging, applies to this research study only.

It is your responsibility to update your mobile/cell phone number with the research study team in the event of a change.

Preferred contact while on study

We will contact you approximately every week via email, phone, or text message (your preference) to see how you are doing and answer questions or concerns. We will only discuss your medical information via phone or face-to-face meeting. Standard fees apply to phone calls, text messages, and emails (depending on your phone plan and data plan).

May we contact you via text message? Yes No

May we contact you via email? Yes No

Preferred method (circle at least one): Phone call Text message Email

Email address:_____

Permission to use data

May we share your de-identified information with other researchers to study cancer and other related projects?

Yes No

Signatures and dates

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

Subject Name (Printed by Subject): _____

Signature of Subject: _____ Date: _____

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

Name and Title (Print):_____

Signature of Person Obtaining Consent:_____

Date: _____