PROTOCOL

Study Title:
Development and Usability Testing of Nutrition Algorithms for Cancer Health Outcomes (NACHO) and Quality of Life During Cancer Treatment

DF/HCC IRB Protocol #22-637

NCT05825469

January 29, 2025

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1.0 Objectives

Aim 1a. Develop preliminary nutrition algorithms based on the Cancer Nutrition Consortium (CNC) study findings[1,2] and iteratively refine through an expert dietitian panel from the DFCI Longwood/Chestnut Hill campus with consultation from oncology clinicians, as needed.

Aim 1b. Refine draft algorithms through feedback from a panel of 4-6 Patient and Family Advisory Council (PFAC) members.

Aim 2a. Evaluate algorithm usability and acceptability with 4-6 oncology clinicians and a second expert dietitian panel from the DFCI satellite locations using semi-structured interviews or focus groups and heuristic evaluation methodology.[3]

Aim 2b. Evaluate algorithm usability and acceptability with 4-6 patients actively undergoing treatment or who have completed primary therapy using semi-structured interviews and heuristic evaluation methodology.[3]

Aim 3 (Exploratory). Assess the usability (i.e., engagement with the web-based nutrition algorithm), acceptability (i.e., completion of feedback questionnaire), and effectiveness (i.e., clinical [e.g., BMI, adverse events], self-reported symptom and QOL questionnaires]) of the algorithm among 100 individuals undergoing chemotherapy treatment for breast, gastrointestinal (GI), lung, or gynecologic cancers, or hematologic malignancies.

We are currently seeking approval to conduct Aim 1a and 1b only. We will submit amendments sequentially to conduct following aims as materials are developed.

As of January 2025, we are opening Aim 2a and 2b.

2.0 Background

2.1 Individuals undergoing treatment for cancer experience an average of 10 co-occurring symptoms[4] that often occur in clusters and negatively impact quality of life (QOL).[5,6] Frequently, individuals experience a GI-based symptom cluster (e.g., nausea, changes in taste, distress).[7] Depending on clinical status and treatments, individuals can also experience constipation, diarrhea, vomiting, mucositis, and other symptoms that can impair nutritional well-being.[8] Notably, there is a high amount of inter-individual variability in these symptom experiences.[4] Some of this variability has been explained by the identification of certain demographic and clinical characteristics associated with high symptom burden groups such as older age,[9] a high body mass index (BMI),[10,11] poor functional status,[12] multiple comorbidities,[12] and poor baseline nutritional status.[2,13] During and following treatments for cancer,

altered nutritional status may be associated with perturbations in inflammatory and metabolic pathways.[14,15] Older age,[9] a high BMI,[10,11] and poor nutritional status[2,13] may contribute to chronic inflammation. Of note, the majority of individuals diagnosed with cancer are over the age of 65.[2] In addition, individuals with cancer who are overweight (i.e., BMI>25 kg/m^2) are at increased risk for worse cancer-related symptoms (e.g., pain, fatigue, depression, sleep disturbance)[16,17] and at the obese level (i.e., BMI>30 kg/m^2), are at increased risk for morbidity and mortality during and following cancer treatments.[18] Being underweight (i.e., BMI<18.5 kg/m^2) increases the risk for poor prognosis and death.[19] During cancer treatment, decreases in nutrient consumption may occur due to treatment-related symptoms (e.g., nausea, vomiting, esophagitis, dysphagia).[20] These nutritional alterations, coupled with chronic inflammation, can lead to dysbiosis (alterations in the gut microbiota) which, in turn, alters immune function.[21,22] Since microbiota aid in the degradation and processing of foods consumed and are integral in the systemic process of metabolism, GI, and cardiometabolic function,[13] it is essential to mitigate damage and/or restore the integrity of the microbiome. Therefore, ensuring good nutrition is critical during and following treatments for cancer.

2.2 Scientific Background and Rationale for the Research

Studies investigating associations between nutrition, inflammation, immune function, symptoms, and QOL in people with cancer are lacking. Information is emerging, however, related to diet, food preferences, and symptom experiences. The Cancer Nutrition Consortium (CNC) conducted a large multi-site study to understand nutritional challenges and preferences of individuals undergoing treatment for breast, GI, lung, or gynecologic cancers, or hematologic malignancies. In one analysis of 800 adults $\geq$55 years old with cancer, fatigue and poor appetite were frequently reported.[2] Similarly, in the parent study of nearly 1200 adults ($\geq$18 years old) with cancer, variability in taste and odor sensitivities, food preferences, and symptom experiences were identified.[1] Notably, individuals who reported decreased appetite, increased sensitivity to certain tastes and smells, and avoidance of certain foods reported decreased energy over treatment time.[1]

In response to the findings from this large study, the CNC enlisted culinary experts to develop nutritional recipes for people with cancer. Recipes are publicly available through the CNC website. Currently lacking is a precision health person-centered approach to providing the best nutritional support based on an individual's

age, BMI, cancer diagnosis, treatments, comorbidities, symptom experiences (e.g., nausea, vomiting, changes in taste, constipation, diarrhea, mucositis),[7,8] preferences, and nutritional needs. Of note, symptom experiences have a temporal nature during and following treatments.[23] Addressing nutritional needs, therefore, need to shift with shifting symptom experiences, health status, preferences, and needs.

One method to addressing shifting care needs is through a person-centered, algorithm-based, clinical decision support metric developed from research evidence.[24,25] Guided by the Model for Symptom Management,[26] the adaptation of clinical guidelines (ADAPTE) methodology,[27] and the findings from the CNC's comprehensive study,[1] this proposed study will develop and evaluate a nutrition recommendation program centered on individual clinical characteristics, GI symptom experiences, and personal preferences. Initial nutrition algorithms will be developed and vetted through panels of expert dietitians, oncology clinicians, and patients with cancer who have completed treatment. In a subsequent study, a technology-based platform will be developed to house the algorithms for the person-centered nutrition program, termed: **N**utrition **A**lgorithm for **C**ancer **H**ealth **O**utcomes (**NACHO**). The final program will include the input of demographic/clinical (e.g., age, BMI, comorbidities, disease type, treatment regimen) characteristics that will drive the algorithms. Decision points will include current patient symptoms and preferences. Individual food and recipe recommendations will be generated for each patient with each interaction with the NACHO program. As patient symptoms, preferences, and treatment regimens change, the recommendations will shift accordingly. Following the development and testing of the prototype, we anticipate subsequent studies that will include evaluation of changes in the microbiome and the incorporation of foods and recipes across diverse cultures. We hypothesize that using NACHO will optimize patient nutritional status and improve QOL.

3.0 Inclusion and Exclusion Criteria

For aims 1a, 1b, 2a, and 2b, subjects include dietitians (1a and 2a), oncology clinicians (2a), members of PFAC (1b), and patients with cancer (actively undergoing treatment or have completed treatment, 2b) in groups of 4-6 each. For aim 3 (exploratory), 100 patients undergoing treatment for breast, GI, lung, or gynecologic cancers, or hematologic malignancies will be included.

3.1 **Inclusion criteria**:

Dietitians/Oncology clinicians

- Have worked with at least 3 patients at the study site who had nutritional challenges
- ***Patient and Family Advisory Council (PFAC) participants***
  - Current member of adult PFAC
  - ≥ 18 years old

Patient participants

- ≥ 18 years old
- Able to speak and read English
- Completed primary treatment (aim 2b) or actively undergoing treatment (aim 2b and aim 3, exploratory)
- Access to a device (e.g., computer, tablet, smartphone) through which they can receive and engage with a REDCap link

Exclusion criteria:

Patient participants

- Provider does not recommend

3.2 **Excluded:**

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners

4.0 **Study-Wide Number of Subjects**

4.1 This single-site study will accrue a sample of up to 30 subjects in formative phases (Aims 1 and 2) and 100 subjects with breast, GI, lung, or gynecologic cancers, or hematologic malignancies to test the algorithms in Aim 3. Efforts will be made to include 20 subjects in each disease group in Aim 3.

Aim	**Subjects (n)**
Aim 1a	Dietitians (4-6)
Aim 1b	PFAC members (4-6)
Aim 2a	Oncology clinicians (4-6) + dietitians (4-6)
Aim 2b	Patients (4-6)
Aim 3	Patients (100)
Overall	*All subjects (N = up to 130)*

5.0 Study-Wide Recruitment Methods

5.1 All subjects will be recruited by DFCI staff. Recruitment methods are outlined in section 22.0.

6.0 Multi-Site Research

NA

7.0 Study Timelines

7.1 Duration of participation in this study will be up to one year from the time of consent.

7.2 It is anticipated that it will take up to three months from study approval to develop and refine the initial algorithms with up to 30 panel members in formative phases (Aims 1 and 2), six months to enroll 100 patient subjects who will be followed for six months, and an additional six months for analyses and dissemination following participant engagement in the study.

7.3 This study, with a final sample of 100 patient subjects and up to 30 panel members, is estimated to be completed by aim, as follows:

- 1a) Develop preliminary nutrition algorithms based on the Cancer Nutrition Consortium (CNC) study findings[1,2] and iteratively refine through an expert DFCI dietitian panel and expert clinician consultations, as needed – June 2023
- 1b) Refine draft algorithms through feedback from a panel of 4-6 Patient and Family Advisory Council (PFAC) members – July 2023
- 2a) Evaluate algorithm usability and acceptability with a 4-6 member DFCI oncology clinician and a second 4-6 member DFCI dietitian panel using semi-structured interviews or focus groups and heuristic evaluation methodology[3] – September 2023
- 2b) Evaluate algorithm usability and acceptability with 4-6 patients (on treatment or have completed treatment) using semi-structured interviews and heuristic evaluation methodology[3] – December 2023
- 3) Assess the usability (i.e., engagement with the web-based nutrition algorithm), acceptability (i.e., completion of feedback questionnaire), and effectiveness (i.e., clinical [e.g., BMI, adverse events], self-reported symptom and QOL questionnaires]) of the algorithm among 100 individuals undergoing treatment for breast, GI, lung, or gynecologic cancers, or hematologic malignancies – December 2024

- 4) Analyze data, disseminate findings, submit grant application for larger scale study including the developing of a web-based application (app) – March 2025

8.0 Study Endpoints

8.1.1 Primary study endpoints: Develop a preliminary nutrition algorithm using the CNC study findings[1] and iteratively refine through an expert dietitian panel with clinician consultation, as needed, as follows:

- Conduct a secondary analysis of the CNC study data to evaluate subgroups of patients by cancer type (i.e., breast, GI, lung, gynecologic cancers or hematologic malignancy), dietary changes (e.g., increased/decreased appetite, food aversions), and outcomes (i.e., changes in energy level, changes in weight) using data collected in the CNC study.[1]
- Develop, review, and refine nutrition algorithms that will provide suggested foods and recipes with the expert dietitian panel of 4-6 members plus clinician consultation over six months.
- Evaluate draft algorithms with a panel of 4-6 PFAC members.

8.1.2 Secondary study endpoints:
2a) Evaluate algorithm usability and acceptability with 4-6 oncology clinicians and a second 4-6 member expert dietitian panel and 2b) a panel of 4-6 patients who have completed primary cancer treatments.

- Using semi-structured interviews and heuristic evaluation methodology[3], we will conduct individual, cognitive interviews and/or focus groups with subjects as they use an interactive system of the algorithm through the Research Electronic Data Capture (REDCap)**[28]** platform. A heuristic evaluation includes the assessment of an interface (e.g., nutrition algorithm) in following pre-specified standard rules (i.e., heuristics) and violations associated with its use.[3] For this study, the heuristics related to the nutrition algorithm decision tree will be evaluated. This is followed by a checklist evaluation of the user interface (with REDCap for this study).

- Following each cognitive interview and/or focus group, participants will complete a questionnaire to quantitatively assess the extent to which the algorithm is engaging, usable, and acceptable. Acceptability is a multi-dimensional construct comprising burden, affective attitudes, subjective experiences, opportunity costs, and intentions to use the

tool.[29] Acceptability of NACHO will be assessed using a survey that includes the System Usability Scale (SUS)[30] and the Acceptability e-Scale (AES).[31] The SUS (Cronbach's α = 0.85) is a 10-item instrument that is widely used to assess the usability of products such as websites and mobile applications. Total SUS scores may range from 0-100, with higher scores representing greater usability. The AES (Cronbach's α = 0.76) is a six-item scale that measures how easy, enjoyable, understandable, and helpful a tool is; whether the participant liked the tool; acceptability of time to complete the tool; and overall satisfaction with the program. Total scores range from 6-30, with higher scores representing greater acceptability. Together, these two tools assess the five dimensions of acceptability. Consistent with published recommendations, we will define acceptability as a SUS score >70 and an AES score >24.[30,31]

8.1.3 Tertiary study endpoint: In this exploratory aim, we will assess the following:

8.1.3.1 Usability will be evaluated as the rate of engagement (i.e., number of times the algorithm is used) with the web-based nutrition algorithm over the course of six months.

8.1.3.2 Acceptability, as described above for the panel member feedback, will include using a five-dimensional construct comprising burden, affective attitudes, subjective experiences, opportunity costs, and intentions to use the tool.[32] The survey will include the User Engagement Scale - Short Form (UES-SF), the System Usability Scale (SUS), the Acceptability of Intervention Measure (AIM), and the Intervention Appropriateness Measure (IAM).

8.1.3.3 Effectiveness will be evaluated by comparing baseline and six-month outcomes of clinical data (e.g., BMI, adverse events) and self-reported symptom and QOL questionnaires among 100 individuals undergoing chemotherapy treatment for breast, GI, lung, or gynecologic cancers, or hematologic malignancies. The questionnaires include: Patient Reported Outcomes Data: National Institutes of Health (NIH) National Cancer Institute (NCI) Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE™),[33] and the Patient-Reported Outcomes Measurement Information System (PROMIS)-10 Global Health Questionnaire v.1.2[34] (all described below).

8.1.4 Safety Endpoints: None

9.0 Procedures Involved

9.1 Study Design: This is a longitudinal, mixed-methods, pilot descriptive study.

9.2 Research Procedures: To accomplish Aims 1a and 1b, expert panel members will contribute to the development of the algorithms. We will request a waiver of written documentation of informed consent for this aim. Aim 1a and 1b participants will self-report basic demographics (Appendix C). After establishing a data transfer agreement, data from the CNC nutritional assessment studies[1,2] will be used to develop the draft algorithms. In an iterative process, input from an expert DFCI dietitian panel will be sought as preliminary algorithms are developed. Oncology clinicians may be included as consultants, as needed. Following the development of draft algorithms, a panel of 4-6 PFAC members will review the refined algorithms. The algorithms will be hosted on the REDCap[28] platform using a secure web authentication, data logging, and Secure Sockets Layer (SSL) encryption process.

To accomplish Aim 2a, oncology clinicians and dietitians will participate in cognitive interviews and/or focus groups in-person in an office or conference room at the clinic site or via a HIPAA-compliant Zoom platform. We will request a waiver of written documentation of informed consent for this aim. Aim 2a participants will self-report basic demographics (Appendix C). Participants will review the algorithms using REDCap on a provided tablet device or personal computer along with a PDF of the full view document of the algorithms that visually show the decision points with branching logic. Interviews and focus groups will be audio recorded, de-identified, and professionally transcribed. Based on participant feedback, Aim 1 expert panel members will review and revise the algorithms.

To accomplish Aim 2b, patient participants will undergo cognitive interviews in-person in a private clinic site area or via a HIPAA-compliant Zoom platform. Patient participants will provide written documentation of informed consent and will self-report demographics; we will collect clinical variables such as diagnosis from the medical record. Patient participants will review the algorithms using REDCap on a provided tablet or personal computer and provide feedback. Interviews will be audio recorded, de-identified, and professionally transcribed.

Once the final version of the algorithm is established, we will test it in a group of 100 patient subjects during active treatment. Subjects will report baseline demographic information via REDCap. At

baseline and monthly for six months, subjects will be prompted by email through REDCap to use the nutrition algorithm. At end of study, subjects will answer symptom and QOL questionnaires as described in 8.1.3.2 and 8.1.3.3. Clinical data such as diagnosis and treatment type will be collected from the medical record.

Dietitians, oncology clinicians, PFAC members, and patients participating in aim 2b will receive $100 gift cards for their contributions to algorithm development. Aim 3 patient participants will receive a copy of the CNC cookbook as an appreciation gift for participating in the study.

Amendments will be submitted to the IRB as materials are developed to begin conducting successive aims of the study.

Table 1. Study activities timeline

Study Activities	Months 1-3	Months 4-6	Months 7-9	Months 10-12	Months 13-15	Months 16-24	Months 25-27
Develop initial algorithms	X, EP						
Interviews		D, OC	P				
Algorithm revisions		X	X				
Enroll patients in 6-month pilot study				X	X		
Monthly prompts to complete nutrition algorithms				X	X	X	
Demographic and clinical data						X	
Symptom and QOL questionnaires						X	
Feedback questionnaire						X	
Analyses, dissemination, subsequent grant preparation						X	X

Legend: EP = expert panel, D = dietitian, OC = oncology clinician, P = patient, X= study team

Data Collection: Demographic/Clinical Data: Demographic data including age, sex at birth, gender identification, ethnicity/race, socioeconomic status, and comorbidity information will be self-reported through the demographic questionnaire. Clinical data (e.g., BMI, adverse events) will be collected from the participant's EHRs at baseline (visit 1) and month 5 (visit 6). Data will be obtained through chart abstractions.

PROMIS-10 Global Health Questionnaire v.1.2[34] is an NIH developed, valid and reliable instrument that will be used to assess functional status and quality of life. This is global health version 1.2 questionnaire consists of 10 questions consisting of Likert scale ranging from 1-5. The 10th pain question is a numeric scale ranging from 1-10. The raw sum score is computed into T-Score distributions, which are standardized such that a 50 represents the average (mean) for the US general population, and the standard deviation around that mean is 10 points. The scores can be computed to identify global physical and mental health component scores. Patients will complete this assessment at baseline, month 2, and month 5 (visits 1, 3, and 6).

Patient Reported Outcomes Data: National Institutes of Health (NIH) National Cancer Institute (NCI) Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE^{TM})[33] is a valid and reliable instrument specific to oncology symptoms. The PRO-CTCAE (eSyms) Symptom Check Questionnaire (DFCI), will be used as outcome measures. Data on sleep quality (i.e., insomnia), will be obtained from protocol 03-189 or collected monthly as part of this study. Additional related symptom cluster of pain, fatigue, and depression (i.e., anxiety, discouraged, sad) will be collected monthly as part of this study.

10.0 Data and Specimen Banking

10.1 N/A

11.0 Data Management and Confidentiality

11.1 **Analysis plan for the exploratory aim.** The rates of usability, acceptability and effectiveness of the algorithm will be reported using descriptive statistics and analyzed using a Fisher's exact test and t-test to determine possible associations with the patients' diagnosis. For effectiveness, the clinical-, self-reported symptom- and the QOL- questionnaires (sub-scales) will also be cross tabulated against the different diagnoses to test for possible associations. The demographics of the whole sample will be

preliminarily assessed to ascertain the balance across the different diagnosis groups; in case of relevant unbalances, the main features will be tested using the weighted versions of either the chi-squared or the Wilcoxon rank-sum tests (according to the outcomes).

11.2 **Power analysis:** This is a descriptive exploratory study that will be used to determine power in a subsequent larger study.

11.3 **Quality control of data:** Data will be monitored and quality checked by the research team. REDCap database's logic checks will be utilized to ensure data quality and minimize missing data.

11.4 **Data handling:** Data and the participant list will be (separately) electronically stored after the study is complete per SOP: Record Retention for Completed Research (RCL-101). The study team is comprised of experienced researchers trained in human subjects' protections. The study staff and all research activities will be monitored by the PIs. The PIs and Project Director will train all study staff in procedures for maintaining participant confidentiality and securing data. All members of the research team will be responsible for immediately reporting breaches of confidentiality or data security to the PIs, compliance office per institutional policy, and the IRB. Risks related to data privacy will be minimized by a series of standardized procedures to maintain strict confidentiality of all data collected by this study.

Only the study team will have access to the data or specimens. All data will be de-identified prior to any analysis. Drs. Hammer and Cooley and their study team will be responsible for all data collection activities including tracking and transmitting of data as necessary. After all participant data are received/collected, they will be shared de-identified for analyses securely.

12.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

12.1 This study is minimal risk and, Adverse Events (AE) for this study are not anticipated. In the event there are AE reports, annual summaries will not include identifiable material.

13.0 Withdrawal of Subjects

13.1 This is a minimal risk study and there are no interventional drugs being tested. Subjects will be able to withdraw at any time with no impact on their current or future medical care or relationship with the Dana-Faber Cancer Institute. Subjects can inform the study

team of wanting to stop or withdraw from the study and all data collection activities will cease.

14.0 **Risks to Subjects**

We anticipate the study to be no greater than minimal risk. Potential risks include feeling upset when answering questions about symptoms and mood. Subjects will be reminded at the start of each questionnaire that they can skip any question or stop at any time. Based on previous similar research, we expect this to be a low probability risk. If a subject scores 3 or higher on PHQ-4 subscales for depression or anxiety, they will be contacted by the study team and referred to their oncologist or social worker.

Another risk is loss of privacy. The study team will take all usual precautions as stated above in section 11.4 to decrease this risk.

15.0 **Potential Benefits to Subjects**

15.1 Participants may find the recommended foods and recipes enjoyable and may benefit from improved nutritional status.

16.0 **Vulnerable Populations**

16.1 Vulnerable populations including pregnant women and prisoners will not be included.

17.0 **Community-Based Participatory Research**

17.1 This study is not community-based participatory research.

18.0 **Sharing of Results with Subjects**

Results will not be shared directly with participants. Findings will be disseminated through publications and presentations without any patient identifiers. Disseminated publications and presentations will be available to participants.

19.0 **Setting**

The study will take place at Dana-Farber involving dietitians and oncology clinicians, and patient participants from selected clinics. Research will be conducted virtually (REDCap, telephone/Zoom, or mail) and in person.

19.0 **Resources Available**

19.1 <u>Dana-Farber Cancer Institute (DFCI)</u>

The study team is well equipped to complete the proposed research. Drs. Hammer and Cooley at DFCI will have all resources available through the Phyllis F. Cantor Center to conduct the study and provide study oversight, including research assistants,

coordinators, and project directors. The Cantor Center is a 1200 square-foot office suite comprised of 7 offices and 16 workstations. The Cantor Center has laptop and desktop computers, telephones, secured filing cabinets, and office appliances (e.g., printers) for study use. The study will benefit from the administrative support of Cantor Center staff (e.g., study coordinators, clinical research assistants, students). The Cantor Center is located within walking distance from the DF/HCC clinical sites and the Department of Biostatistics.

Due to the COVID-19 Pandemic, research activities have transitioned to a remote format. Following institutional guidelines. The Cantor Center is located in a non-clinical building at 375 Longwood Avenue. Per guidelines, e-consents will be used when needed to minimize in-person study visits.

Principal Investigators:
Marilyn Hammer, PhD, DC, RN, FAAN is the Director, Phyllis F. Cantor Center for Research in Nursing and Patient Care Services

Mary Cooley, PhD, RN, FAAN is a nurse scientist in the Phyllis F. Cantor Center for Research in Nursing and Patient Care Services.

Co-Investigators:

Rachel Pozzar, PhD, RN, FNP-BC is an Instructor at Harvard Medical School and nurse scientist in the Phyllis F. Cantor Center for Research in Nursing and Patient Care Services.

Emanuele Mazzola, PhD is a biostatistician in the Department of Biostatistics at the Harvard T.H. Chan School of Public Health.

Katherine McManus, MS, RD, LDN, is the Director, Department of Nutrition, Brigham and Women's Hospital.

Other study personnel:
A Project Director from the Cantor Center will guide the coordination, facilitation, and data management of this study.

CRCs from the Cantor Center will identify and enroll subjects and aid in data collection

20.0 **Prior Approvals**

N/A

21.0 **Recruitment Methods**

Aim 1a Dietitians: Dietitians will be identified through the DFCI Nutrition Department, and a recruitment email will be sent with study information including elements of consent (Appendix A). Those interested will have the option of responding by email or calling a member of the study team. The first 4-6 dietitians who meet the study criteria and express interest will be invited to participate.

Aim 1b PFAC Members: PFAC members will be identified through the DFCI PFAC staff liaison and program coordinator, and a recruitment email will be sent with study information including all elements of consent (Appendix B). Those interested will have the option of responding by email or calling a member of the study team. The first 4-6 PFAC members who meet the study criteria and express interest will be invited to participate.

Aim 2a Dietitians/Clinicians: Dietitians will be identified through the DFCI Nutrition Department, and an email will be sent describing the study. Those interested will have the option of responding by email or calling a member of the study team. The first 4-6 dietitians who meet the study criteria and express interest will be invited to participate. To recruit oncology clinicians, the PI will introduce the study to oncology clinicians at an interdepartmental meeting. The first 4-6 oncology clinicians who meet the study criteria and express interest will be invited to participate.

Aims 2b and 3 Patients: The study team will screen patients from the DFCI breast, GI, lung, gynecologic, and hematologic cancer clinic groups for eligibility. The study will be presented at faculty meetings. Emails will be sent to primary providers providing the opportunity to opt their patients out of recruitment. If a participant is not opted out, a recruitment letter will be sent via US mail or Patient Gateway to the potential participant containing study information and a copy of the ICF. The potential participant will have one week to opt out via phone, email, or text from being further contacted. Those who do not opt out will receive a call by a member of the study team to further describe the study and assess for participation interest. For those interested, the study team member will review the ICF with the potential participant (or schedule a more convenient time to review the study materials).

A partial HIPAA waiver will be requested, if needed, to screen and recruit patient participants only (Aim 2b and 3).

22.0 **Local Number of Subjects**

22.1 For Aim 1a, up to 6 dietitians will form a panel to develop the algorithms. For Aim 1b, up to 6 PFAC members will review and provide feedback on the algorithms. For Aim 2a, up to 6 oncology clinicians and up to 6 additional dietitians will be interviewed or participate in focus groups. For Aim 2b, up to 6 patients will be interviewed. For Aim 3, 100 pilot study patient subjects will be recruited and enrolled. Subjects will be recruited and enrolled at DFCI only.

23.0 **Provisions to Protect the Privacy Interests of Subjects**

All study related data, inclusive of the screening and enrollment logs will be kept in a secure, encrypted database that requires authenticated login and password protection; consent forms will be locked in study offices at the Dana-Farber Cancer Institute in the Cantor Center or stored on MGB shared networks; individually identifiable private information will be accessible only to study staff who are trained in the protections of human subjects and study procedures and IRB approved.

24.0 **Compensation for Research-Related Injury**

24.1 This is a minimal risk study, research related injury not anticipated

25.0 **Economic Burden to Subjects**

25.1 There are no costs that participants may be responsible for due to participation in the study.

26.0 **Consent Process**

26.1 For Aims 1a, 1b, and 2a, we will request a waiver of written documentation of consent. The investigators will email dietitians, PFAC members, and oncology clinicians an invitation to participate, outlining study procedures and all required elements of consent. For Aims 2b and 3, we will obtain written informed consent from patient participants.

26.2 We will follow DF/HCC Policy CON-100: Informed Consent Process. For all participants, a consent discussion will take place by telephone, Zoom, or in clinic following a recruitment script which covers all elements of consents and includes asking the subject after each section if they have any questions. Study staff will be trained in detail by the PD on use of the recruitment script and ensuring that subjects are not coerced to participate. Patient participants will have received a blank hard copy of the consent form or an electronic copy through Patient Gateway or REDCap, while dietitian and clinician participants will have received a copy of

the study information sheet via e-mail. Subjects may agree to participate at the time of the consent review, or after additional time to consider and discuss participation with others. The consent discussion is expected to require at least 10 minutes and up to as long as the subject needs, including multiple discussions, to answer all their questions and make a decision about participating. Subjects will be asked to provide written documentation of consent by mail or REDCap.

26.3 The study will not be enrolling subjects who are not yet adults, cognitively impaired adults, or adults who are unable to consent.

27.0 **Process to Document Consent in Writing**

27.1 We will follow DF/HCC Policy CON-100: Informed Consent Process. When written documentation of informed consent is obtained, it will be obtained via mail (paper consent form) or electronically through REDCap. Participants who provide consent electronically will be instructed on how they can save a copy of their signed consent form, and those who sign with ink will receive a copy by secure Dropbox link or U.S. mail.

28.0 **Drugs or Devices**

28.1 The study does not involve any drug or device use.

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