SUBJECT INFORMATION AND INFORMED CONSENT FORM – Control Group

Official Title: Optimizing the Delivery of Diabetes Management During Cancer Care

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BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC

WEILL CORNELL MEDICAL COLLEGE
SUBJECT INFORMATION AND INFORMED CONSENT FORM – Control Group

Protocol Title: Optimizing the Delivery of Diabetes Management During Cancer Care
Protocol #: 22-07025006
Sponsor: National Cancer Institute
Principal Investigator: Laura C. Pinheiro, PhD, MPH
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KEY INFORMATION ABOUT THIS RESEARCH STUDY

You are being asked to be a subject in a research study because you have cancer and pre-diabetes or type 2 diabetes.

The following table is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in the research.

Purpose	This is a research study to evaluate the co-management of diabetes and cancer.
Voluntary Participation	Your decision to be in this study is voluntary.
Withdrawal	If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.
Length of Participation	Your participation is expected to last up to twenty weeks. The length of time you are in this study and number of study visits depends on the date of your first cancer treatment. It may last up to two years.
Risks	There are not expected to be any physical risks to you as part of this study.
Benefit	There is no guarantee that you will benefit as a result of your participation in this study, however the study results may help people in the future.
Alternative to Study Participation	There may be other options for treatment of your condition including creating a treatment plan with your doctor.
Costs	The study sponsor will pay for the cost of the procedures that are required only for the study.
Confidentiality	There are provisions in place by the study protocol and study site to help protect the privacy and confidentiality of your personal health information and study information.

This overview does not include all of the information you need to know before deciding whether or not to take part. Much additional detail is given in the full

consent document, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

INFORMED CONSENT FORM

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the study doctor and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your primary care physician. If you agree to take part in this research study, you must sign this consent form.

DISCLOSURE OF FINANCIAL INTERESTS
The National Cancer Institute, the sponsor of this study, is providing funds to WCM/NYPH on a per subject basis for conducting this research study.

PURPOSE OF THE STUDY
The purpose of this study is to evaluate the safety and effectiveness of a new diabetes care plan for patients with cancer.

NUMBER OF SUBJECTS AND LENGTH OF STUDY PARTICIPATION
About 76 subjects are expected to participate in this study at 3 research sites in New York City.

Your participation in this study is expected to last 20 weeks.

STUDY PROCEDURES
A research assistant will ask you to complete a 45-minute survey during your first cancer treatment visit. The survey can be completed on paper or using a tablet (online). At your last treatment, we will collect additional information such as number of visits to the emergency departments, urgent care visits, and/or hospitalizations. There will also be a second survey we will ask you to complete at this time. Similarly, this survey can be completed on paper or using a tablet. We will also ask you for feedback about your experience with the Patient Activated Learning System, which you will have access to during this study. This learning system contains educational models and a search option to help answer your questions regarding your diagnoses and treatments. We will review your medical records after the follow-up survey to record number of cancer treatment planned and attended, and if there were any changes to your treatment or missed treatments.

SUBJECT RESPONSIBILITIES
As a subject in this study, you will have certain responsibilities, including the following:
- Attend all study visits and, if needed, reschedule appointments as soon as possible
- Follow the instructions of the study team
- Tell the study doctor all medications that you are taking and check with the study doctor before taking any new medicines (including prescription, over-the-counter, vitamins and herbal supplements)
- Tell the study staff any time you do not feel well or if you have any side effects

RISKS AND DISCOMFORTS
The risks are minimal to no risks. All privacy and confidentiality risks will be minimized by storing all data on a password-protected secure network. Some of the survey questions may cause emotional distress. All psychological risks will be minimized by protecting subjects' rights and emphasizing that participation in this study is voluntary and subjects have the right to stop at any time.

NEW INFORMATION
You will be notified in a timely way if important new findings become known that may affect your willingness to continue in the study.

Clinically Relevant Research Results
The overall results of this study may or may not be available to you at the end of the study. The study doctor will also explain if and when you will receive individual research results that may have clinical significance.

BENEFITS
There is no guarantee that your condition will improve as a result of your participation in this study. It may stay the same or worsen. However, the information learned from this study may help other people with this disease in the future.

ALTERNATIVES TO STUDY PARTICIPATION
You do not have to participate in this study to receive treatment for your condition. The alternative is to not participate. The study doctor will discuss study alternatives with you and their risks and benefits.

COSTS OF PARTICIPATION
The sponsor will cover the cost of assessments and procedures required only for this study.

You and/or your insurance company will be responsible for the costs of all items and services during the research study, which you would have received for your condition if you were not enrolled in this research study and/or that your physician believes are medically necessary to treat you. You should discuss possible costs of study participation with the study staff and/or your insurance company.

REIMBURSEMENT
You will not receive reimbursement for each visit toward your study related expenses such as travel and parking.

You will receive a $25 gift card at the beginning of the study and a $50 gift card at the end of the study .

Tax law may require the payer (e.g. research institution or third party) to report the amount of payment you receive from that payer to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally this reporting would take place if you receive $600 or more from the payer in a calendar year. You would be responsible for paying the taxes on the payment you received from the study.

COMPENSATION FOR INJURY
For medical emergencies, call 911.

Because this study involves only the sharing of medical information and requires no specific procedures, tests, or treatments, no research-related injuries are expected. No financial compensation will be offered by the sponsor or Weill Cornell Medicine or the Biomedical Research Alliance of New York. You are not waiving any legal right to seek additional compensation through the courts by signing this form.

CONFIDENTIALITY

To the extent allowed by law, every effort will be made to keep your personal information confidential. However, information from this study will be submitted to the study sponsor and to the U.S. Food and Drug Administration. It may be submitted to governmental agencies in other countries where the study product may be considered for approval. Medical records, which identify you and the consent form signed by you, will be looked at by the sponsor or the sponsor's representatives and may be looked at by the FDA and other regulatory agencies, the WCM Institutional Review Board, and the Biomedical Research Alliance of New York. While these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/ or publications.

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.

AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about laboratory test results
- Results from diagnostic and medical procedures including but not limited to X-rays, physical examinations and medical history
- Billing records

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration
- Department of Health and Human Services agencies
- Governmental agencies in other countries
- Biomedical Research Alliance of New York (BRANY)
- The WCM Institutional Review Board
- Accrediting agencies
- Data safety monitoring boards
- Health insurers and payers
- Other individuals and organizations that analyze or use your information in connection with these research activities, including laboratories, contract research organization and study sites (if you transfer to another study site)

Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these

groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose. The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care and you will not lose any benefits or legal rights to which you are entitled. You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Certificate of Confidentiality: To help us protect your privacy, the study doctor has applied for a Certificate of Confidentiality from the Department of Health and Human Services. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal agency. 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 written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

<u>Collection of Identifiable Private Information or Identifiable Biospecimens</u>:

- Your information and biospecimens collected as part of this research study, even if

identifiers are removed, will not be used or distributed for future research studies.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Your participation in this study is voluntary. You may decide not to participate or you may stop your participation at any time, without penalty or loss of benefits or medical care to which you are otherwise entitled. If you decide to leave the study, please tell the study doctor.

Your participation in this study may be stopped without your consent at any time and for any reason by the study doctor, the sponsor, the FDA and other regulatory authorities. Reasons you may be withdrawn from the study include it is determined to be in your best interest, you need treatment not allowed in this study, you do not follow the study instructions, the study is stopped, or for other administrative reasons. If you leave the study early, you may be asked to return to the study doctor's office for a final study visit for your safety.

CONTACTS FOR QUESTIONS, COMPLAINTS, CONCERNS
If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Dr. Laura Pinheiro at 646-962-5898.

If you have any questions about your rights as a research subject or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research.

STATEMENT OF CONSENT - SIGNATURES
By signing this form, I confirm the following:

- I have read all of this consent form.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of my personal health information and study information collected as part of this study by the sponsor and other authorized persons and regulatory agencies as described in this form.
- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.

I voluntarily agree to participate in this study.

Subject: Name (Print)	Signature	Date
Person Obtaining Consent: Name (Print)	Signature	Date