Document Coversheet

Study Title: POW-R Health: Power to Redefine your Health (Internal Title: A Pragmatic Dietary Intervention to Improve Bladder Cancer Survivorship)

Institution/Site:	Roswell Park Comprehensive Cancer Center
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ROSWELL PARK CANCER INSTITUTE

Title: POW-R Health: Power to Redefine your Health Program ***(Internal Title: A Pragmatic Dietary Intervention to Improve Bladder Cancer Survivorship)***

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Roswell Park Study Number: I 661820

Consent Form Given to Patient Taking Part in an Investigational/Clinical Research Study

KEY INFORMATION ABOUT THIS RESEARCH STUDY

This is a research study being done by the doctors at the Roswell Park Comprehensive Cancer Center and the National Cancer Institute. Research studies include only those patients who choose to take part. It's up to you whether you want to be a part of this study. Please take your time to make your decision. Talk with your family and with people who are important to you.

We are asking you to take part in this study because you have been diagnosed and treated for bladder cancer. The goal of this study is to make a healthy eating program to improve cancer outcomes. The purpose of this study is to compare two types of healthy eating programs. This study will allow the researchers to know whether different types of healthy eating programs can improve the bladder cancer outcomes of the patients.

Study Costs: The intervention that you will receive as part of this study will be given to you at no cost. The study is funded by the National Institutes of Health and the National Cancer Institute.

Study Duration and Number of Participants: It is expected this study will take about two years or will continue until the needed number of participants is enrolled. This study will include about 80 bladder cancer patients within New York State.

Your participation in this study will be for 6 months. The study team will contact you by phone at the beginning of the study and again after 6 months to ask you survey questions. During the program you will receive health education materials, a phone call (approximately 45-60 minutes) along with 11 automated phone calls that will ask about how many vegetables you ate the previous week.

Research Tests and Procedures: If you take part in this study you will be asked to do the following:

1. You will be interviewed to complete survey questionnaires twice over a 6-month period (one time at the beginning of the study and another time at the end of the study). Each survey will take about 45-60 minutes. You will complete these surveys over the phone

with a study staff member. The surveys will include questions about you (for example, age, education, gender, spirituality/faith), what you eat, bladder cancer history, and current lifestyle.

2. You will be asked to report what you ate and drank over the past 24 hours. This will take about 20 minutes each time. You will be asked to report this on 3 randomly selected days at the start of the study, and then 3 randomly selected days at the end of the study. You will complete this over the phone with a study staff member.
3. You will be asked to give urine samples at the start and end of the study. At the start of the study, you will be asked to give your first morning urine sample for three days, and then again at the end of the study we will ask you to do this again. We will give you instructions for collecting the urine at home and we will ask you to ship it back to Roswell Park in a postage paid shipping box that we will give you.
4. You will receive 11 Interactive Voice Response (IVR) phone messages.

Section 3 of this document gives more information about the study.

Side Effects and Risks: For the survey portion of the study, being a part of this study does not involve any physical risk. You may feel uncomfortable answering questions.

There are no known risks from giving a urine sample.

Potential Benefits: Participants in the healthy eating program may get better eating habits from being a part of the study and/or reduce the risk of their bladder cancer from coming back. You understand there is no guarantee that being in the study will help you. Future participants may be helped from the results and information gained from this study.

Other Options: It is your decision to join. There are no penalties for not taking part in this study.

The type of study, the risks, benefits, discomforts, and other important information about this study are below.

DETAILED INFORMATION ABOUT THIS RESEARCH STUDY

It is important that you read and understand the following facts that apply to anyone that takes part in this study:

a) This study is considered research. It is investigational, which means, we're trying to figure out what type of healthy eating program is best for bladder cancer participants.
b) Taking part in the study is voluntary. You don't have to be a part of this study. It's up to you to be a part.
c) You may stop being a part of the study at any time without penalty, loss of any benefits or access to care at Roswell Park to which you are otherwise entitled.
d) If you should decide not to take part in this study, it will not affect your care at Roswell Park now or in the future.
e) Your disease may not be helped from taking part in this study, but we may get information that will help others.
f) If we become aware of important new information that may relate to your willingness to participate this study, we will inform you of this new information.

1. What is the purpose of this study?

The study's goal is to make a healthy eating program to reduce cancer recurrence and/or progression in bladder cancer patients. Our overall goal is to develop a healthy eating program that could easily be delivered through clinics serving bladder cancer patients, and to reduce bladder cancer recurrence and progression for a lot of patients.

This study is being done by the researchers and doctors at the Roswell Park, and is sponsored by the National Institutes of Health/National Cancer Institute.

2. What are the study groups?

This study involves random (by chance) placement to receive one of two healthy eating programs. Both programs will be based on the most up-to-date science. Neither you nor the study staff can choose which healthy eating program you will get. You will not know which healthy eating program you will get. Randomization is a process used to place patients in different programs or groups. A statistician will use a computer to assign the groups. By using randomization, the groups will be similar and the programs they receive can be compared objectively. You will have an equal chance of being placed in either group.

You will be randomized to one of two groups (healthy eating program A or healthy eating program B).

Both groups will learn how to eat healthier through setting goals and receiving feedback on their current eating habits. Both groups will get: 1) mailed educational materials about eating healthy, healthier eating goals, and the importance of keeping track of what you eat; 2) one phone call from study staff to make sure you understood the educational materials you received; and 3) 11 Interactive Voice Response (IVR) phone messages that will begin by asking you many servings you ate of certain foods.

Groups A and B will differ in the types of food that are focused on to eat healthier.

3. If I take part in this study, what tests and procedures will I have done?

What Procedure/Test?	How?	When? How often?
Study explained; eligibility screening; signed informed consent to be a part of the study	By phone, 15 minutes	Start of study
The three-day first morning urine collection	Self-collected by participant and shipment by mail	Start of study, end of study (6-months)
Survey	By phone, 45-60 minutes	Start of study, end of study (6-months)
3 Dietary recall (how many servings you ate of certain foods)	By phone, 20 minutes for each recall	Start of study, end of study (6-months)
Study treatment: 1) Group 1 (n=40) will receive healthy eating program A by phone 2) group 2 (n=40) will receive healthy eating program B =by phone	By mail, phone and automated phone message	6-month program after survey and dietary recalls.

4. Will I be informed of the research results?

If we learn new information from research tests or analyses during this study that may be important to your health or to your disease or condition, we will share that information with you. Such information will be provided to you if you ask from them.

5. Could I be taken off the study early?

You may be taken off the study if:

- You do not do what the study asks you to do
- New information becomes known to us that would change your decision to stay in the study
- The Principal Investigator or the sponsor of the study decides to stop or change the study
- Your medical condition changes
- You no longer want to be a part of the study

6. What risks and discomforts are involved?

For the survey parts of the study, there is no physical risk. There are no known risks from giving urine samples.

7. Are there any reproductive risks?

There are no known reproductive risks with being a part of this study.

8. What are my responsibilities in this study/What will I be asked to do?

If you choose to take part in this study, you will be asked to:

- Complete study surveys over the phone at 2 different time points over the course of 6 months
- Complete six dietary recalls over the course of 6 months
- Provide a urine sample of 10 mL each day for three days at 2 different time points over the course of 6 months
- Be a part of the healthy eating program assigned to you

9. What will this cost?

There are no costs to be a part of this study other than your time.

10. What happens if I am injured as a result of this study?

If you believe you have been injured as a direct result of being part of this research study, call the Roswell Park Patient Advocate at (716) 845-1365 or Dr. Yeary at (716) 845-1300 Ext 6231 or Dr. Li Tang (716) 845-8247.

Medical diagnosis and treatment for the injury will be offered, and a determination will be made regarding appropriate billing for the diagnosis and treatment of the injury. A financial counselor can be reached at 716-845-3161 to provide an explanation of coverage and to answer questions you may have about study related billing.

You do not give up any legal rights by signing this form. You are not prevented from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research.

11. Will I be paid for joining this study?

You will be paid $100.00 for each assessment (each time data is collected), as noted in the table below.

	Start of study	End of study (6 months)
Survey and urine sample	$40	$40
Dietary recall 1	$20	$20
Dietary recall 2	$20	$20
Dietary recall 3	$20	$20

This research may result in developing treatments, devices, new drugs, or procedures that could be used for commercial profit by the sponsor or other entities. If this happens, you understand that you will not receive any financial payment or share in any commercial profit for the use of your information and urine samples collected as part of this research.

12. Where can I find more information?

You may call the NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) for information on cancer-related questions and cancer clinical trials.

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.

For accurate cancer information including Physician Data Query (PDQ) cancer information summaries, visit https://www.cancer.gov.

13. Who do I contact with questions?

You are free to ask questions at any time about this study and to ask for more information from the researchers named on this document. If you have any questions, concerns or complaints about this study, contact the study researchers named on the first page of this document. In case of an emergency after regular hospital hours, call (716) 845-2300 and ask for the bladder doctor on call.

If you have questions about your rights as a research subject or you feel you have been injured as a result of being a part of this research study, you can call the Roswell Park Patient Advocate (Support) Office at (716) 845-1365. Feel free to contact the Patient Advocate Office at any time while considering being a part of this study, when you're a part of this study or once you've finished being a part of this study. This office is not connected with any specific research study. They can help you get more information about being a part of research and your rights as a research subject or how to proceed if you feel you have been injured as a result of being part of the study. They are there to talk about any problems, concerns, questions or input you may have.

We may have to contact you in the future to give you new information about the study. For this reason, we ask that you call the Patient Access office at 716-845-1049 to update us of any change in your address.

14. Conflict of Interest Statement

- The National Cancer Institute pays for the conduct of this study, including part of Dr. Yeary's and Dr. Tang's salary.

- Any questions regarding financial conflict issues can be directed to your doctor or to Donald J. Handley, MBA, MS, Executive Director Research Subject Protections, who can be reached at 845-3455. These disclosures are made so that you can decide if this relationship will affect your willingness to participate in this study.

CONFIDENTIALITY AND USE OF HEALTH INFORMATION

If you decide to take part in this research study, and you sign this document, you give permission to the study investigators and research staff to use or release your health information that identifies you and is collected as part of the research study described in this consent. However, we will make every effort to maintain confidentiality. Your urine samples and survey data will not have your name on it and will be linked only by a unique number. Analysis will only be performed by putting data from many patients together; we will not be looking specifically at your information alone. However, others involved in conducting the study may know or be able to find out your identity, use your health information, and share it with others. We want you to know who may use this information and how they may use it. We also want to tell you about your rights before you agree to take part in the study.

Who may see this information?

- Dr. Yeary and Dr. Tang and key members of the study/research team at Roswell Park
- Government or Regulating Agencies such as the FDA, DHHS, NCI, NIH or other agencies working with authorized study monitors, auditors and clinical research organization representatives.
- Institutional Review Boards or Data Safety and Monitoring Boards at Roswell Park and its affiliates or outside of Roswell Park.
- Above Ground Development (AGD) is the outside company that will be responsible for setting up the 11 Interactive Voice Response (IVR) phone messages.

What information may be collected, used and shared?

Health information that identifies you and relates to your participation in this study will be collected and created. This may include the following:

- Health information, sometimes known as "Protected Health Information" (PHI) can include your name; address; patient identification number; medical record number; date of birth; photographs; information about your health, including past medical history, treatment, diagnosis, test results and any other information about your health or medical condition; if you are a patient at Roswell Park, PHI can also include payment of charges for medical treatment found in your medical record or other records at Roswell Park.
- Information from the procedures used to find out whether you are eligible to take part in this study. This may include information that you may release to us, including information about your health history.
- Information obtained in the course of the study including information about your response to any treatments you receive, information related to study visits and phone calls, urine tests, and any other information about you being a part of this study.
- Your name, date of birth and phone number will be collected and shared using a secure website with Above Ground Development (AGD), this is the company that Roswell Park has contracted with that will be responsible for conducting the Interactive Voice Response phone messages.

Why will this information be used and/or shared?

PHI and other information that may identify you can be used and may be given out to those listed above to carry out the research study. This information may also be shared with other governmental agencies in this country only when it is required. The information may also be used to meet the reporting needs of governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be shared.

Your de-identified information may also be stored in a research database or repository. This de-identified information may then be used for other research, with further IRB review and approval. Your identify will not be shared with other research. This information will be kept indefinitely unless you request that your information should not be kept.

What if I decide not to give permission to use and give out my health information?

If you do not allow the collection and use of your health information as written above, you will not be able to be in this research study.

Your decision not to sign this document or to withdraw from the study will not involve any penalty or loss of benefits to which you are otherwise entitled and will not affect your access to non-research related health care.

What happens if I want to withdraw my authorization?

You may change your mind and take back this authorization at any time, except to the extent that Roswell Park has already used or disclosed health information based on this authorization. To revoke/withdraw this authorization, you must write to the study researcher (name and address is on the first page of this form) and let the researcher know that you are withdrawing your authorization to use and disclose your information.

If you should die while enrolled in or after taking part in this study, your health information may be used or disclosed solely for research purposes without getting any added authorization.

Your health information or urine samples collected as part of the research, even if all information that does or can identify you is removed, will not be used or given out for future research studies.

May I review or copy the information obtained from me or created about me?

You will not have the right to review or copy aspects of your Protected Health Information (PHI) that are considered to impact the integrity (truthfulness) of this research study. At the end of this research study and at your written request, you may have access to your health information that relates to the research study. This information is kept in your medical record, which is a set of data that includes medical information or billing records used in whole or in part by your doctors or other health care providers at Roswell Park to decide about care and treatment. Access to your health information in your medical record is described in the Notice of Privacy Practices provided to you by Roswell Park. If it is necessary for your care and/or treatment, your PHI will be provided to you or your referring or primary care doctor. You will not have access to your blood, tissue, and diagnostic research study results that are performed in a laboratory/facility that is not approved to report clinical results.

If it is necessary for your care and/or treatment, your health information will be provided to you or your referring or primary care doctor.

When does this authorization end?

This authorization does not have an end date.

What happens to my health information after it is given to others who are not subject to the federal privacy laws and may no longer be protected?

If you sign this form, the information collected from you may be shared with those listed above.

There may also be times when your personal health information is shared with someone who is not subject to the federal privacy laws. Examples of people and organizations that may not have to follow the federal privacy laws are sponsors of the research study and some researchers. Even though some organizations are not covered entities under these federal privacy laws, many of them follow state or other national laws that protect your information.

There is always a risk that this information may be re-disclosed without your permission to third parties who are not subject to the same laws as those in the United States and may no longer be protected. However, the study investigators and study team have protections in place to assure the security of your health information.

Authorization

As a participant in this study, you agree to allow the use of your health information for research. You understand that your health information will be used by Roswell Park as described in this document. You understand that you have a right to take away your authorization for use of your health information in writing, but the information which has already been used or disclosed before your written withdrawal will continue to be used for research purposes unless you request your information should not be kept. Finally, you understand your health information that has been disclosed through this authorization may be further disclosed to organizations that are not covered entities, and the health information will no longer be protected by the federal privacy laws.

As an additional measure to protect your privacy, a Certificate of Confidentiality has been issued from the United States Government, National Institutes of Health, for this study. With this Certificate, the investigators and institutions involved in this study 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 proceeding. We will use this Certificate to resist any demands for information that would identify you, with the following exceptions:

- The Certificate cannot be used to resist a request for your information from the United States Government when the information is to be used for auditing or evaluation of federally funded projects or for information that must be disclosed to meet the requirements of the Food and Drug Administration (FDA).
- State law requires we report cases of diseases that spread easily, or abusive behavior (toward a child, a partner, or an elderly person), and people who say they are going to hurt themselves or someone else.
- The Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or involvement in this research. Also, if you have given written consent to an insurer, employer, or other person to receive research information, then we may not use the Certificate to withhold the information.

Statement of Investigator/Person Conducting the Informed Consent Discussion:
I certify that the nature and purpose, the potential benefits and possible risks associated with being a part of this research study have been explained and that any questions about this information have been answered. A signed copy of this consent will be given to the participant.

SIGNATURE_____ **DATE**_____ **TIME**_____

PRINTED NAME _____

Participant's Statement of Consent:
By signing below, you agree that:

- You have been told of the reasons for this study.
- You have had the study explained to you.
- You have had all of your questions answered, including those about areas you did not understand, to your satisfaction.
- You have carefully read this consent form and will receive a signed copy of this form.
- You do **not** waive any **legal** rights you have under federal or state laws and regulations.
- You willingly give your consent to voluntarily join in this research study.

Participant:

SIGNATURE_____ **DATE**_____ **TIME**_____

PRINTED NAME _____

Witness Signature is needed in the following circumstances – check below:
☐ Not Applicable
☐ The person consenting cannot write – mark must be made as appropriate.
☐ The person consenting cannot read - consent has been read to him/her.
☐ The person consenting cannot understand English and the consent has been verbally interpreted.
(The witness should be fluent in both English and the language of the person consenting.)

Witness Statement:

The person consenting has signed this document in my presence.

SIGNATURE_____**DATE**_____ **TIME**_____

PRINTED NAME _____

RELATIONSHIP TO PARTICIPANT_____

CONSENT HANDLING
Original to CRA-Regulatory with Race/ Ethnicity if applicable
Copy to:

- Patient
- CRS Registration
- Medical Records