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Official Title: Giving Information Systematically and Transparently in Lung and GI Cancer

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WEILL CORNELL MEDICAL COLLEGE

Informed Consent and HIPAA Authorization for Clinical Investigation

Project Title: Giving Information Strategically and Transparently in Solid Tumor Cancer

Project #: 19-07020392

Principal Investigator: Holly G. Prigerson, PhD

Group: Patient

Patient Name: _____

Institution: Weill Cornell Medical College

INTRODUCTION

You are invited to consider participating in a research study. You were selected as a possible participant in this study because you are a patient with solid tumor cancer.

Please take your time to make your decision. It is important that you read and understand several general principles that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary.

(b) Personal benefit to you may or may not result from taking part in the study, but knowledge gained from your participation may benefit others;

(c) You may decide not to participate in the study or you may decide to stop participating in the study at any time without loss of any benefits to which you are entitled.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other information about the study are discussed below. Any new information discovered which might affect your decision to participate or remain in the study will be provided to you while you are a participant in this study. You are urged to ask any questions you have about this study with members of the research team. You should take whatever time you need to discuss the study with your physician and family. The decision to participate or not to participate is yours. If you decide to participate, please sign and date where indicated at the end of this form.

The research study is being funded by the Department of Medicine at Weill Cornell Medical College. Dr. Holly Prigerson is the primary investigator.

The study will primarily take place at Weill Cornell Medicine (NYC). Some portions of the study may take place by phone. Some portions of the study may take place at facilities of NewYork-Presbyterian Hospital. NewYork-Presbyterian Hospital is neither a sponsor nor an investigator for this study.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to pilot a new informal oncologist training that we call GIST—Giving Information Strategically and Transparently. We hope GIST will help oncologists better communicate information to their patients, and for patients to better understand the details about their prognosis as well as what their options are and what those options mean for their future.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participants in the study are referred to as subjects. About 50 patient subjects and 4 physician subjects will take part in this study at this site.

WHAT IS INVOLVED IN THE STUDY?

Your oncologist will either have been trained or not have been trained in the Oncolo-GIST method. You will receive care as normal. The study involves the same commitment regardless of whether your oncologist is GIST-trained.

Your participation in the study will involve two initial interviews:

1. The first interview will take place when you enroll in the study and will take approximately 25 minutes.
2. The second interview will take place after you have an imaging scan and discuss the results with your oncologist, within one week of the appointment. It will take approximately 20 minutes.

We may ask you to complete **two** additional surveys in the future. These would also take place after you have an imaging scan and discuss the results with your oncologist. Each of these surveys would take approximately 20 minutes.

You can choose whether to do the surveys at home on the computer (via a secure internet link); over the phone; or in person (during or after a treatment appointment).

The interviews will include questions that ask about:

- Strategies you are using to cope with your illness
- Your physical, psychological, and social wellbeing
- How your oncologist explains scan results and treatment options to you
- Your prognosis and intent of the treatment(s) you are receiving

If you become upset or tired during the interviews, the interviewers will ask you if you would like to take a break or reschedule the interview for another time. If you become very upset during or after an interview, we will ask you to speak with your healthcare team or with Dr. Heather Derry, who is a psychologist on the research study team. Dr. Derry can help put you in touch with a mental health professional if you would like to speak with one.

We will also review your medical records periodically to collect information about your cancer, other health conditions, and treatments and procedures you are receiving. We will record this information from your medical chart each time we survey you.

This study is being done in addition to the normal care that you will receive from your healthcare team, and will not affect your treatment. Your responses will not be shared with your medical team, unless you explicitly request to do so, or if you express risks to your health or safety.

HOW LONG WILL I BE IN THE STUDY?

You will be in the research study for up to 12 months

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first.

If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with WCMC, New York-Presbyterian Hospital, your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

WHAT ARE THE RISKS OF THE STUDY?

There are risks to taking part in any research study. The risks associated with this study are small. There are no risks of physical injury. The interviewer will ask you questions about how you have been coping with your illness and about your mental health (depression, anxiety). You may find yourself becoming emotional when discussing these topics.

You have the right to not answer a question or stop the interview at any time. If you experience difficulty answering the questions, please refrain from pushing yourself to the point of discomfort. If you find the interview has upset you and you want to talk with someone, please contact your healthcare team for immediate needs. You may also contact the study Principal Investigator, Dr. Holly Prigerson, Ph.D. at (212) 746-1374 for concerns that are not urgent.

Risks from Invasion of Privacy: Given that your personal responses will be gathered by the researchers, there is a risk of loss of confidentiality. Every effort will be made to protect your privacy.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this research study, we cannot and do not guarantee that you will receive any benefits from this study. We hope the information learned from this study will benefit other patients with cancer in the future.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you may choose not to participate in this research study. Participation, discontinuing participation, or lack of participation will not affect your relationship with Weill Cornell Medicine.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of study participants are stored and kept according to legal requirements and may be part of your medial record. You will not be identified personally in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as:

- Representatives of Weill Cornell Medical College and New York-Presbyterian Hospital
- The Institutional Review Board (IRB)
- The Office of Human Research Protection (OHRP)
- Department of Health and Human Services and National Institutes of Health
- The Food and Drug Administration (FDA) and/or their representatives
- National Institutes of Health and/or their representative will have access to your files.

By signing this consent form, you authorize access to this confidential information. You also authorize the release of your medical records to Weill Cornell Medical College and NewYork-Presbyterian Hospital by any other hospitals or institutions where you might receive medical care of any kind while you are participating in this study.

If information about your participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage by requiring a unique ID and password to log into the database. We will keep a password-protected spreadsheet with subjects' identifying information that will be stored on the secure WCM shared drive, accessible only by appropriate study personnel. We will keep your identifying information separate from your responses to study questions, and will instead us a unique Study ID number to identify your responses. In addition, only personnel who are associated with the study will have access to the study specific records in the database.

HIPAA AUTHORIZATION TO USE or DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Purposes for Using or Sharing Protected Health Information: If you decide to join this study, WCMC researchers need your permission to use your protected health information. If you give permission, Weill Cornell Medical College (WCMC) and/or New York-Presbyterian Hospital (NYPH) researchers may use your information or share (disclose) information about you for their research that is considered to be protected health information.

Voluntary Choice: The choice to give WCMC and/or NYPH researcher's permission to use or share your protected health information for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission for WCMC and/or NYPH researchers to use or share your protected health information if you want to participate in the study. If you decline to sign this form, you cannot participate in this study, because the researchers will not be able to obtain and/or use the information they need in order to conduct their research. Refusing to give permission will not affect your ability to get usual treatment, or health care from WCMC and/or NYPH.

Protected Health Information To Be Used or Shared: Government rules require that researchers get your permission (authorization) to use or share your protected health information. Your medical information may be disclosed to authorized public health or government officials for public health activities when required or authorized by law. If you give permission, the researchers could use or share with the entities identified above any protected health information related to this research study from your medical records and from any scan results.

Other Use and Sharing of Protected Health Information: If you give permission, the researchers could also use your protected health information to develop new procedures or commercial products. They could share your protected health information with the study sponsor, the WCMC Institutional Review Board, inspectors who check the research, government agencies and research study staff.

The information that may be shared with the sponsor and/or government agencies could include your medical record and your research record related to this study. They may not be considered covered entities under the Privacy Rule and your information would not be subject to protections under the Privacy Rule.

You may agree to allow your data, tissue, and/or blood sample(s) to be used for future research either within or outside WCMC and/or NYPH. If information goes to an outside entity then the privacy rule may not apply.

Confidentiality: Although the researchers may report their findings in scientific journals or meetings, they will not identify you in their reports. Also, the researchers will try to keep your information confidential, but this cannot be guaranteed. The government does not require everyone who might see your information to keep it confidential, so it might not remain private.

CANCELING AUTHORIZATION

Canceling Permission: If you give the WCMC and/or NYPH researchers' permission to use or share your protected health information, you have the right to cancel your permission whenever you want. However, canceling your permission will not apply to information that the researchers have already used or shared.

If you wish to cancel your permission, you may do so at any time by writing to:

Privacy Officer
1300 York Avenue, Box 303
New York, NY 10065

If you have questions about this, call: (212) 746-1179 or e-mail: privacy@med.cornell.edu

End of Permission: Unless you cancel it, permission for WCMC and/or NYPH researchers to use or share your protected health information for their research will never end.

ACCESS TO RESEARCH RECORDS

During the course of this study, you will have access to see or copy your protected health information as described in this authorization form in accordance with Weill Cornell Medical College (WCMC) and/or New York-Presbyterian Hospital (NYPH) policies. During your participation in this study, you will have access to your research record and any study information that is part of that record.

WHAT ARE THE COSTS?

Taking part in this research study will not lead to added costs to you or your insurance company.

POLICY/PROCEDURES FOR RESEARCH RELATED INJURY

Compensation for wages, time lost, disability or discomfort is not available. You do not give up any of your legal rights by signing this consent form.

The Policy and Procedure for Weill Cornell Medical College are as follows:

We are obligated to inform you about WCMC's policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from WCMC or New York-Presbyterian Hospital. Further information can be obtained by calling the Institutional Review Board at (646) 962-8200.

COMPENSATION FOR PARTICIPATION

You will receive $25 for each assessment (the two initial surveys, and two possible follow-ups, for a possible total of $100) in this research study. You will receive $25 after each assessment is completed.

You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose to not take part in the study or to leave the study at any time. If you choose to not participate in the study or to leave the study, your regular care will not be affected nor will your relations with the Weill Cornell Medical College, New York-Presbyterian Hospital, your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Dr. Prigerson at (212) 746-1374. Dr. Prigerson's office is located at Weill Cornell Medical College, 413 East 69th Street, 604 Belfer Research Building, New York, NY 10065. If you are calling after hours, please call Dr. Prigerson at (617) 459-3304. Be sure to inform the answering service of your participation in this research study.

If you have questions about your rights as a research participant, contact the WCMC IRB Office. Direct your questions to:

Institutional Review Board at:

Address: 1300 York Avenue
Box 89
New York, New York 10065

Telephone: (646) 962-8200

Consent for Research Study

Project Title: Giving Information Simply and Transparently in Solid Tumor Cancer

Principal Investigator: Holly G. Prigerson, PhD.

RESEARCHER'S STATEMENT

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____	_____	_____
Signature of person obtaining the consent (Principal Investigator or Co-investigator)	Print Name of Person	Date

SUBJECT'S STATEMENT

I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I otherwise am entitled. I agree to cooperate with Dr. Holly Prigerson and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

_____	_____	_____
Signature of Subject	Print Name of Subject	Date