



CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY Patient

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Source of Support: National Cancer Institute

Study Title: CONNECT: Care Management by Oncology Nurses – A Cluster Randomized Trial

This is a research study for people who have metastatic cancer (cancer that has spread from the part of the body where it started to other parts of the body), and their family members, who are receiving care at a UPMC Cancer Center clinic. The Principal Investigator is Yael Schenker, MD, MAS from the University of Pittsburgh, Division of General Internal Medicine. A staff member will explain this study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating, and discuss your decision with your family or friends if you wish. If you have any questions, you may ask the researchers.

Why is this research being done?

Patients with metastatic cancer and their family members often experience unmet supportive care needs. Symptoms such as pain, emotional distress, and difficulty coping are not uncommon. You are being asked to participate in a research study to test whether a specially-trained oncology nurse working together with a patient's cancer doctors can help. We hope to learn how to improve quality of life for patients with metastatic cancer and their family members.

Who is being asked to take part in this research study?

You are being asked to participate in this study because you are a patient with metastatic cancer who is receiving care at a UPMC Cancer Center clinic.

A total of 672 patients and their family members (or friends) will be invited to take part in this study.

What will happen if I take part in this research study?

If you decide to take part in this research study:

- We will assess whether you are eligible for participation in this study by talking with your doctors here at the UPMC Cancer Center clinic and by reviewing your medical information.

If you are not eligible for the study, we will send you a letter in the mail to let you know. We will not review your records further once this determination has been made.

If you are eligible for the study:



- We will contact you to let you know that you are eligible for the study. At that time, you and your family member (or friend) will be asked to schedule a time to complete a confidential baseline survey.
 - For the baseline survey, we will ask you basic demographic questions, as well as questions about any symptoms you may be experiencing, your quality of life, your mood, your understanding of your illness, and your treatment preferences.
 - This will be done by telephone or via a paper survey. It should take approximately 20 minutes to complete.
- Approximately 3 months from your enrollment, we will contact you to conduct a confidential follow-up survey.
 - This will include questions about any symptoms you may be experiencing, your quality of life, your healthcare utilization, your mood (including questions about symptoms of anxiety and depression), your understanding of your illness, and your treatment preferences.
 - This will be done by telephone or via a paper survey. It should take 20-30 minutes to complete.
- We will contact you (and/or your family member or friend) by phone monthly for up to one year to ask about healthcare utilization. These phone calls should take less than 5 minutes.
- We will review your medical record for up to one year to gather information about your cancer, your functional status, visit and treatment dates, and the types of treatment you are receiving.
- Your oncologist will be informed of your participation in the study and your consent form may be added to your medical record. Participating clinics have been randomized to one of two groups. At some clinics, your doctors and nurses will continue to provide standard oncology care, as well as any other services that you or your doctors feel you need. At some clinics, your doctors and nurses will continue to provide standard oncology care, any other services that you or your doctors feel you need, as well as additional supportive care (provided via the CONNECT intervention). If your clinic has been randomized to the CONNECT intervention, the following will occur:
 - An initial visit with you, your family member or friend (if available), and a CONNECT oncology nurse who has received special training in how to address supportive care needs. This visit will take place at the Cancer Center clinic on the same day as your next regularly scheduled oncology appointment. You may be asked to come a little bit early for your visit and/or stay a little bit late. If you do not have an oncology appointment scheduled within one month, we will schedule a special visit for you to see the CONNECT nurse. If you are unable to come in for a visit, the nurse will call you to talk on the phone. The first visit will focus on getting to know you as a person, identifying a medical decision maker, and addressing any symptoms you may have.
 - Follow-up visits at least once a month for approximately 3 months. These visits will take place at the Cancer Center clinic on the same days as your regularly scheduled oncology appointments. You and your family member or friend (if available) may be asked to come a little bit early for these visits and/or stay a little bit late. If you do not have regular oncology appointments at least monthly, we will schedule special visits for you to see the CONNECT nurse. If you are unable to come in for a visit at least monthly, the nurse will call you to talk on the phone. These visits will focus on addressing any symptoms you may have, discussing your preferences and goals, and helping you to make decisions about your care.
 - You, your family member or friend (if available), and the CONNECT nurse will complete a Shared Care Plan (SCP). Your SCP will document the plan for addressing any symptoms you may have and discussions between you and the CONNECT nurse about your preferences and goals. You and your family member will be given a copy of the SCP at the end of each visit and asked to bring your SCP to the next visit. You will be encouraged (but not required) to discuss your preferences and goals with your family and to ask your oncologist any questions you may have about your cancer care. The CONNECT study nurse will also share your SCP and any needs you



identify with your oncologist.

- You, your family member or friend (if available), and the CONNECT nurse will complete an advance directive. An advance directive is a form that will help you to document the kinds of things that are important to you in the future. The CONNECT nurse may share the preferences you identify on the advance directive form with your oncologist.
- The CONNECT nurse may document the symptoms, preferences and goals that you discuss during a study visit in your medical record, in order to ensure that your care is coordinated and other providers are aware of your needs. The advance directive form that you complete may be added to your medical record.
- Some visits with the CONNECT nurse will be audio-recorded. The purpose of audio-recording is to help us to improve supportive care.
- You will be asked to complete a brief (less than 5-minute) questionnaire before each supportive care visit about how you have been feeling.
- You will receive a telephone call from the CONNECT nurse within approximately one week of each visit to check in about how you are doing.

Study location: Study procedures will take place in a private or semi-private exam room or space at the Cancer Center clinic or by telephone.

How long will I be in the study?

Your participation in the study will last for up to 1 year.

What are the possible risks, side effects, and discomforts of this research study?

Some of the questions we will ask you as part of this study may make you uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer. If you are receiving care at a clinic with additional supportive care visits, it is possible that participating in these visits may be a burden to you. We will make every attempt to conduct these visits on the same day as your oncology visits. Some people may feel self-conscious about being audio-recorded. It is unlikely, but possible, that a breach of confidentiality/loss of privacy may occur. To reduce the likelihood of this, all researchers have been thoroughly trained to protect your privacy and data confidentiality.

What are possible benefits from taking part in the study?

Some people who participate in the study may benefit from the services offered. The information that you share will help us to learn how to best care for patients with metastatic cancer and their families.

What other choices do I have if I do not take part in this study?

You are free to choose not to participate in the study. If you choose not to participate in this study, you will receive usual medical care for your condition without any additional research procedures. You may change your mind about participation in the study at any point, and you may skip any survey questions you do not wish to answer.

What are the costs of taking part in this study?

There are no costs for participating in this study.

Will I be paid for taking part in this study?

You will receive \$30 upon completion of the 3-month survey.

Who will have access to identifiable information related to my participation in this research study?



Any information obtained about you from this research will be kept as confidential (private) as possible. Your name will not be used in any published reports about this study. We will use an ID number instead of your name to label the study information gathered from you. Your ID number and name will be kept in a password-protected computer in a locked office.

If you are receiving care at a clinic with additional supportive care, the CONNECT nurse will be working closely with your oncology team to help ensure that your needs are met. This means that any information you share with the CONNECT nurse may be shared with your oncologist or nurse practitioner, including your level of distress, symptom ratings, and shared care plan. This information may be placed in your medical record to ensure that your care is coordinated.

However, your responses to the baseline and 3-month surveys are collected for research purposes and will NOT be shared with your oncology team. Similarly, the audio-recordings of your visits will be kept confidential and will NOT be shared with your oncology team.

In addition to the study investigators and research staff, the following individuals will or may have access to identifiable information related to your participation in this study, for the purpose of research, quality assurance, and/or data analysis:

- Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office.
- Authorized research personnel at the University of Pittsburgh Center for Research on Health Care.
- Authorized representatives of the study sponsor, the National Institute of Health

If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.

We will protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University.

Your research data may be shared with investigators conducting similar research; however, this information will be shared in a de-identified manner.

Certificate of Confidentiality from the National Institutes of Health

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project. You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of harm to self or others. The Certificate of Confidentiality will not be used to prevent disclosure for any



purpose you have consented to in this informed consent document, such as including research data in the medical record.

Will this research study involve the use or disclosure of my identifiable medical information?

We are also requesting your permission to review your medical records. The information that will be recorded includes: your cancer type and stage, date of cancer diagnosis, other diagnoses, and your healthcare utilization. We will use this information to determine whether you are eligible for the study, keep track of how you are doing, coordinate your supportive care visits with your oncology visits (if your clinic has been randomized to the CONNECT intervention) and assess for any impact of the intervention. Your name will not be used in any published reports about this study. We will use an ID number instead of your name to label the information gathered from your medical records. The link connecting the ID number with your name will be kept in a password-protected computer in a locked office.

For how long will the investigators be permitted to use and disclose identifiable medical information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable medical information related to your participation in this research study for as long as it takes to conclude the study (i.e., indefinitely).

Is my participation in this research study voluntary?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. Your choice to participate or not participate will not affect your relationship with UPMC or your doctor in any way. No matter what decision you make, there will be no penalty to you.

Can I stop being in the study?

Yes. You can decide to stop participating in the study at any time. If you decide that you do not want to participate in the study, please call the study coordinator. You may withdraw from the study one of two ways:

1. You may request no further contact about the study but still allow previously-collected information to be used for study purposes, or
2. You may request that all previously-collected information be destroyed.

You can also withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in the study.

The researchers may stop you from taking part in this study at any time if they believe it is in your best interest, if you do not follow the study plan, or if the study is stopped.

Who can answer my questions about the study?

You can talk to the researcher(s) about any questions or concerns you have about this study. You may also contact Dr. Yael Schenker, the Principal Investigator for this study at 412-864-2375 (office phone) or 412-204-6117 (cell phone).



VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that have occurred during my participation.

By signing this form, I agree to participate in this research study and provide my authorization to share my medical records with the research team. A copy of this consent form will be given to me.
If you wish to participate in this study, you should sign below.

Participant's Signature

Printed Name of Participant

Date

Contact Address

Phone Number

Secondary Phone Number

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent

Role in Research Study

Signature of Person Obtaining Consent

Date

Time AM / PM

