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CONSENT FORM

URCC 1701: Dyspnea in Cancer Patients.

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URCC 1701: Dyspnea in Cancer Patients.

INTRODUCTION:

This consent form describes a research study and what you may expect if you decide to participate. You are encouraged to read this consent form carefully and to ask the person who presents it any further questions you may have before making your decision whether or not to participate.

You are being asked to participate in this research study because you have received your first cycle of chemotherapy treatment for cancer.

This form describes the known possible risks and benefits and describes what other choices for care or service are available to you if you do not wish to be in the study. You are completely free to choose whether or not to participate in this study.

Why is this study being done?

Shortness of breath, or dyspnea, is a common side effect experience by patients undergoing chemotherapy treatment. It can result from cancer or its treatment, and can result from both physical or emotional changes. This study is being conducted by the University of Rochester Cancer Center and its affiliates in the Community Clinical Oncology Program to determine whether an FDA approved anti-anxiety drug called buspirone hydrochloride may be helpful in reducing dyspnea in people undergoing chemotherapy treatment. In addition, we hope to discover how prevalent dyspnea is, how symptoms of dyspnea, fatigue, depression and anxiety are related, and if the drug can improve patients' quality of life.

How many people will take part in the study?

Approximately 376 subjects will take part in this study nationally.

What is involved in the study?

You will be assigned by random selection to receive either the anti-anxiety drug buspirone hydrochloride or a pill with no active medication called a placebo. Random selection means that whether you will receive either the buspirone or the placebo is determined by chance, like flipping a coin. The chance of receiving the buspirone or the placebo is approximately equal. Neither you nor the investigators will know during the study what treatment you receive unless there is a medical necessity.

On the seventh day after your second chemotherapy cycle, you will begin taking the study medication. You will take one tablet at bedtime for three days. Then you will take 2 tablets each day, one when you get up in the morning and one when you go to bed, for the remainder of the study period. You will take the study medication for 28 days, even if your chemotherapy is changed or discontinued. After the 28-day study period, you can choose to receive the drug buspirone at your own expense.

In addition, you will complete several paper and pencil questionnaires at two time points: the first time is 5-7 days after your chemotherapy, but before you begin taking study medication or placebo; and the second set of questionnaires are completed 28 days later when you have finished the study medication or placebo. These questionnaires measure the occurrence of shortness of breath (dyspnea), fatigue, depression and anxiety. It takes approximately half an hour to fill out the questionnaires each time; this can be done at home and mailed back using a stamped, addressed envelope which will be provided to you. A staff member will telephone you to remind you to complete and return the questionnaires.

Clinical and demographic information will be obtained from your medical record.

How long will I be in the study?

You will be in the study approximately 28 days. You will complete questionnaires just before beginning study medication or placebo, take the pills for 28 days, then complete the forms again after finishing the study medication or placebo.

What are the risks of the study?

The most commonly observed reactions to buspirone are dizziness, nausea, headache, nervousness, lightheadedness and excitement. Your physician and nurse will be monitoring you closely to see if any of the side effects are occurring.

In rare instances, patients taking serotonin reuptake inhibitor medications (SSRIs), along with buspirone have reported symptoms of serotonin syndrome, which include confusion, sweating, fever, muscle in coordination, and muscle twitching or spasm. If you experience any of these symptoms while you are on the study, you should stop taking your study medication immediately and call your physician as soon as possible.

Buspirone should not be taken at the same time as drugs used to treat depression called monoamine oxidase inhibitors (such as Nardil[®], Marplan[®], Parnate[®]) or within 14 days of stopping treatment with a monoamine oxidase inhibitor, as serious, sometimes fatal reactions may occur. At least 14 days should pass after stopping the study drug before a monoamine oxidase inhibitor is begun. You should avoid drinking alcohol while taking the study medication.

This treatment has not been shown to be free of potential side effects to a fetus. Therefore, pregnancy must be avoided by all women and their sexual partners while undergoing this therapy.

Are there benefits to taking part in the study?

It is not possible to predict whether you will receive any personal benefit from participating in this research study.

What other options are there?

An alternative to participating in this study is not to participate. Buspirone may also be prescribed by your physician outside of this protocol. You may discuss other treatment options with your doctor.

What about confidentiality?

While we will make every effort to maintain your confidentiality, it cannot be absolutely guaranteed. Medical records which identify you and the consent form signed by you may be inspected by the US Department of Health and Human Services (DHHS), the sponsor (National Cancer Institute), US Food and Drug Administration (FDA), the Northwest Community Clinical Oncology Program (NWCCOP), and/or the University of Rochester. The results of this research study may be presented at meetings or in publications; however, your identity will not be disclosed in those presentations.

The federal Health Insurance Portability and Accountability Act (HIPAA) requires us to get your permission to use health information about you that we either create or use as part of the research. This permission is called an Authorization. We will use your research record, related information from your medical records, results of laboratory tests, results of diagnostic procedures, both clinical and research observations made while you take part in the research, screening logs, and case report forms.

We will use your health information to conduct the study, to monitor your health status, to measure effects of drugs/procedures and to determine research results. Health information is used to report results of research to sponsors and federal regulators. It may be audited to make sure we are following regulations, policies and study plans. If you have never received a copy of the Northwest CCOP's HIPAA Notice, please ask to investigator for one.

If you decide to take part, your Authorization for this study will not expire unless you cancel (revoke) it. The information collected during your participation will be kept indefinitely. If you cancel your Authorization, you will also be removed from the study. You can always cancel this Authorization by writing to the study investigator. However, standard medical care and any other benefits to which you are otherwise entitled will not be affected. Canceling your Authorization only affects uses and sharing of information after the study investigator gets your written request. Information gathered before then may need to be used and given to others. For example, by Federal law, we must send study information to the FDA for drug and device studies it regulates. Information that may need to be reported to FDA cannot be removed from your research records.

As stated in the section on Voluntary Participation below, you can also refuse to sign this consent/Authorization and to be part of the study. You can also tell us you want to leave the study at any time without canceling the Authorization. By signing this consent form, you give us permission to use and/or share your health information as stated above.

What are the costs?

There are no added costs associated with your being in this research study. The medication will be provided to you free as part of this study.

Is there compensation for injury?

In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. No funds have been set aside to compensate

you in the event of injury. You or your insurance company will be charged for continuing medical care and/or hospitalization. You will receive no payment for taking part in this study.

What are my rights as a participant?

Participation in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason, without risking loss of present or future care you would otherwise expect to receive. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.

Whom do I call if I have questions and problems?

For questions about the study or a research-related injury, contact *the Northwest Community Clinical Oncology Program, 253-403-1461*. For questions about your rights as a research participant, call *MultiCare Health System Institutional Review Board at 253-403-3844*. The Institutional Review Board (IRB) is a group of people who review research studies to protect your rights.

The physician(s) involved with the medical care of the patient is available to answer **ANY** question(s) concerning the research/drug program. In case of a problem or an emergency, the physician should be contacted by telephone (see cover sheet).

Where can I get more information?

You may call the NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) or TTY: 1-800-332-8615

Visit the NCI's Web sites...

CancerTrials: comprehensive clinical trials information <http://cancertrials.nci.nih.gov>.

CancerNet™: accurate cancer information including PDQ <http://cancer.net.nci.nih.gov>.

You will get a copy of this form. You may also request a copy of the protocol (full study plan).

Signature

You are deciding whether or not to take part in this study. If you sign, it means that you have decided to volunteer to take part in this study and your tumor tissue will be taken and used for the special testing described as part of this study, and that you have read and understood all the information on this form.

Patient's name (printed or typed)

Patient's Signature Date

Physician name (printed or typed)

Physician Signature Date

Signature of person conducting the
Informed consent discussion

Date

**Authorization (Permission) to Use or Disclose (Release)
Identifiable Health Information for Research**

Participant's Name: _____

Birth Date: _____

1. What is the purpose of this form?

The University of Rochester (URCC) is an organization that does research to learn about the causes of cancer, and how to prevent and treat cancer. Researchers would like to use your health information for research. This information may include data that identifies you. Please carefully review the information below. If you agree that researchers can use your personal health information, you must sign and date this form to give them your permission.

2. What personal health information do the researchers want to use?

The researchers want to copy and use the portions of your medical record that they will need for their research. If you enter a URCC research study, information that will be used and/or released may include the following:

- the history and diagnosis of your disease;
- specific information about the treatments you received, including previous treatment(s) you may have had;
- information about other medical conditions that may affect your treatment;
- medical data, including laboratory test results, tumor measurements, CT scans, MRIs, x-rays, and pathology results;
- information on side effects (adverse events) you may experience, and how these were treated;
- long-term information about your general health status and the status of your disease;
- data that may be related to tissue and/or blood samples that may be collected from you; and
- numbers or codes that will identify you, such as your social security number and medical record number.

You may request a blank copy of the URCC data forms from the study doctor or his/her research staff to learn what information will be shared.

3. Why do the researchers want my personal health information?

The Northwest Community Clinical Oncology Program (Northwest CCOP) will collect your health information and share it with the URCC Biostatistical Center and the URCC Operations Center if you enter a cooperative group research study. The URCC centers will use your information in their cancer research study. You are being asked to take part in a study known as URCC 1701: Dyspnea in cancer patients. This study is to determine whether an FDA approved anti-anxiety drug called buspirone hydrochloride may be helpful in reducing dyspnea in people

undergoing chemotherapy treatment. In addition, we hope to discover how prevalent dyspnea is, how symptoms of dyspnea, fatigue, depression and anxiety are related, and if the drug can improve patients' quality of life. This drug is supplied free of charge.

4. *Who will be able to use my personal health information?*

The Northwest CCOP will use your health information for research. As part of this research, they may give your information to the following groups taking part in the research. The Northwest CCOP may also permit these groups to come in to review your original records that are kept by the Northwest CCOP so that they can monitor their research study.

- the URCC Operations Center;
- the URCC Biostatistical Center;
- National Cancer Institute (NCI)
- Public Health agencies and other government agencies (including non-U.S.) as authorized or required by law;
- other people or organizations assisting with URCC research efforts, the company(ies) sponsoring the research); and
- central laboratories, central review centers, and central reviewers. The central laboratories and review agencies may also give your health information to those groups listed in the five bullets above.

5. *How will information about me be kept private?*

The URCC will keep all patient information private to the extent possible, even though the URCC is not required to follow the federal privacy laws. Only researchers working with the URCC will have access to your information. The URCC will not release personal health information about you to others except as authorized or required by law. However, once your information is given to other organizations that are not required to follow federal privacy laws, we cannot assure that the information will remain protected.

6. *What happens if I do not sign this permission form?*

If you do not sign this permission form, you will not be able to take part in the research study for which you are being considered.

7. *If I sign this form, will I automatically be entered into the research study?*

No, you cannot be entered into any research study without further discussion and separate consent. After discussion, you may decide to take part in the research study. At that time, you will be asked to sign a specific research consent form.

8. What happens if I want to withdraw my permission?

You can change your mind at any time and withdraw your permission to allow your personal health information to be used in the research. If this happens, you must withdraw your permission in writing. Beginning on the date you withdraw your permission, no new personal health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your permission.

If you sign this form and enter the research study, but later change your mind and withdraw your permission, you will be removed from the research study at that time.

To withdraw your permission, please contact the person below. She will make sure your written request to withdraw your permission is processed correctly.

Karyn Hart, RHIT, CCRP
Program Coordinator
Northwest CCOP
315 Martin Luther King Jr., Way
Tacoma, WA 98405
(253) 403-1461

9. How long will this permission last?

If you agree by signing this form that researchers can use your personal health information, this permission has no expiration date. However, as stated above, you can change your mind and withdraw your permission at any time.

10. What are my rights regarding access to my personal health information?

You have the right to refuse to sign this permission form. You have the right to review and/or copy records of your personal health information kept by Northwest CCOP. You do not have the right to review and/or copy records kept by the URCC or other researchers associated with the research study.

Signatures

I agree that my personal health information may be used for the research purposes described in this form.

Signature of Patient
or Patient's Legal Representative: _____ Date: _____

Printed Name of Legal Representative (if any): _____

Representative's Authority to Act for Patient: _____

Signature of Person Obtaining Permission: _____ Date: _____

Printed Name of Person Obtaining Permission: _____