



Research Information Sheet

Title of Study: Psychometric Evaluation of the Oncology Nurse Navigator Patient Assessment[®] (ONNPA[®])

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Faculty Sponsor: Fort Lewis College, Department of Public Health

Funder: Fort Lewis College Internal Grants Office

Contact Name and Phone Number for Questions\Problems about Research-Related Health Problems:

[fill in the Medical Oncologist's name and office phone number]

Introduction

You are being invited to take part in this research study because you have been recently referred to a cancer nurse navigator to connect you with the most appropriate care. This study is being led by Dr. Nora Flucke at Fort Lewis College in Durango, Colorado, and is about testing a newly developed assessment tool that supports the work of nurse navigators.

Purpose

The study is being conducted to test the new assessment tool that helps oncology nurse navigators identify patient barriers and needs with the goal of improving health outcomes in cancer care.

Study Procedures

If you take part in the study, you will be asked to let your nurse navigator share some of his/her assessment information with the researchers so that they can test if the new assessment tool works as intended. In the study, assessment information will be treated anonymously to protect the patients' identities.

The information that your navigator would be sharing is part of a routine nurse navigator assessment. In this sense, no action or extra time is required from you to participate in the study.

If you agree to participate you would allow your nurse navigator to share the following information with the researchers **completely anonymously**: age, gender, race, zip code, occupation, insurance type, cancer type and stage, current distress score, and whether you have had a personal and family history of cancer. In addition, the nurse navigator would share information about your needs or barriers to cancer care.

You have the option to not let your nurse navigator share certain information and remain in the study.

If you were to participate in the study, your nurse navigator would work with you as usual. However, after the first meeting, and again right before you start cancer treatment, the nurse navigator would submit some of your assessment information to be entered in the study. The time span in between the first and the second assessments can vary but is expected to average 8 weeks.

Benefits

As a participant in this research study, there may not be any direct benefit for you; however, information from this study may benefit other people now or in the future.

Risks

There are no foreseeable risks from participating in the study beyond what patients can expect from a typical nurse navigation intake assessment for cancer care planning. We will do our best to protect the information we collect from you during this study. We will not collect any information that will identify you to further protect your confidentiality and avoid any potential risk of an accidental breach of confidentiality.

Alternative Procedures

Patients are free to choose whether to become participants in the study. If you are opting not to participate, you can expect nurse navigation services as usual.

Costs

There will be no costs to you for participation in this research study.

Compensation

You will not be paid for taking part in this study.

Confidentiality

All information collected about you during this study will be stored without any identifiers (that means anonymously). No one will be able to match you to your assessment information. No master list of identifiable information will be stored.

Your privacy is important to us, and we will follow federal and state privacy laws, including HIPAA. We will only use the health information we collect to conduct this research study. Only the research team, the Fort Lewis College Institutional Review Board, and federal

agencies that oversee research will have access to this information. Your permission to use the information we collect for this research study will not expire unless you tell us you want to cancel it. We will keep clinical information without identifying elements indefinitely.

Liability

In the event that you suffer a research-related injury, your medical expenses will be your responsibility or that of your third-party payer, although you are not precluded from seeking to collect compensation for injury related to fault or blame on the part of those involved in the research. The Colorado Governmental Immunity Act determines and may limit Fort Lewis College's legal responsibility if an injury happens because of this study. Claims against the College must be filed within 180 days of the injury.

Voluntary Participation/Withdrawal

Taking part in this study is voluntary. You may choose not to take part in this study, or if you decide to take part, you can change your mind later and withdraw from the study at any time. In that case, your information will be deleted.

Questions

If you have any questions about this study now or in the future, you may contact me, Nora Flucke, at the following phone number (970) 247-7188. If you have questions or concerns about your rights as a research participant, you may contact the Chair of the Institutional Review Board, Alex Borgella at (970) 247-7486.

Participation

Your participation is voluntary, and you may refuse to participate without penalty or discrimination at any time.

We strongly advise that you keep a copy of this Research Information sheet for your records.

If you have any questions about this research or would like to know the results of the study, please contact Nora Flucke (970) 247-7188.

If you have questions about your rights as a research participant, contact Becky Clausen (970) 247-7237 or Missy Thompson (970) 247-7580.

The Fort Lewis College Counseling Center can be reached Monday through Friday 8:00 a.m. to 12:00 p.m. and 1:00 p.m. to 5:00 p.m. (MT) at (970) 247-7212.