**Informed Consent for the**

***Psychometric Evaluation of the Oncology Nurse Navigator Patient Assessment© (ONNPA©) Study***

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**Informed Consent Form for Participating Patients**

This informed consent form is for all people who come for care at the _____ [Cancer Center] and who we are inviting to participate in a research study to test the Oncology Nurse Navigator Patient Assessment© (ONNPA©). The title of our research project is:

Psychometric Evaluation of the Oncology Nurse Navigator Patient Assessment© (ONNPA©)

Name of Principal Investigator: Nora Flucke, PhD, RN, CCCTM, CNE
Name of Organization: Fort Lewis College, Durango, Colorado

Name of Co-investigator: Colleen Sullivan-Moore, RN, CN-BN, MS
Name of Organization: Liminal Patient Navigation Consultants, LLC

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent form.

**PART I: Information Sheet**

**Introduction**

We are Dr. Nora Flucke and Colleen Sullivan-Moore. We are a research team who have been working together since 2014 to make improvements in the field of cancer navigation. We are doing research on a new tool that nurses can use to assess the needs of their patients who have been newly diagnosed with cancer. We are going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in our study. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask us to stop as we go through the information, and we will take time to explain. If you have questions later, you can ask the nurse or the staff to connect you with us. We will be happy to answer any questions as they come up.

**Purpose of the Research**

People who are newly diagnosed with cancer might experience many physical, mental, and social barriers to getting the best cancer treatment for their needs. Nurse navigators ask their patients about potential barriers so that those barriers can be identified and resolved quickly. However, nurse navigators need assessment tools, in form of questionnaires, to consistently ask all of their patients what they might need before starting cancer treatment. The Oncology Nurse Navigator Patient Assessment© (ONNPA©) is such a tool that helps nurses do their job effectively and efficiently. The reason we are doing this research is to test if the tool really works to help nurse navigators identify and reduce barriers to cancer care consistently.

**Type of Research Intervention**

This study involves that your nurse navigator fills out the ONNPA© questionnaire with your information. Your nurse navigator might ask you to respond to questions during your first visit and again right before you start cancer treatment a few weeks later.

**Participant selection**

We are inviting all adults who are newly diagnosed with cancer to participate. However, if you are less than 18 or older than 89 years old, are currently pregnant, or are receiving cancer care while in prison you are not eligible to sign up.

**Voluntary Participation**

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this cancer center will continue as usual and nothing will change. If you choose not to participate in this research project, you will be assessed as it is routinely done by your nurse navigator. You may change your mind later and stop participating even if you agreed earlier.

**Procedures and Protocol**

When you come in to meet your nurse navigator for the first time, you will be asked to answer some standard questions about yourself. The questions will be used by the nurse navigator to find out what the nurse navigator can do to get you ready to receive treatment for the cancer. The nurse navigator will use the questions from the ONNPA© questionnaire to find out what you need and which particular physical, mental, and social barriers might be in the way of getting you into treatment quickly. The nurse navigator will then be working with you for a few weeks to try to remove all barriers that could delay your care. At the end, the nurse navigator will record which needs and barriers might be left at the time when you start treatment.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about your well-being or the well-being of other participants, we might have to stop the study. If there is anything you are concerned about, or that is bothering you about the research, please talk to your nurse navigator or one of the other staff members.

**For any Clinical Study:**

The nurse navigator will pass along your de-identified (that means anonymous) information from the ONNPA© questionnaire to the researchers. The researchers will then take the information from all patients together to study whether the ONNPA© questionnaire is helping nurse navigators identify and reduce barriers to cancer care. The system is set up so that everyone who participates in the study will stay nameless. Your privacy is ensured because the nurse navigators will not share any patient names or date of birth information with the researchers. Even the nurses themselves will stay anonymous in this study.

**Description of the Process**

1. During the first visit with the nurse navigator, you will be asked up to 42 questions that are on the ONNPA© form. Most of the questions relate to needs or barriers to care that are common among people who have received a new cancer diagnosis. Some of the questions are personal in nature but you may skip any question you are not willing to answer.
2. During your last visit with the nurse navigator, you will be asked some of the same questions again. The researchers are interested in finding out whether there are less needs and barriers reported on the ONNPA© form after you and your nurse navigator had time to work on overcoming the identified barriers.

**Duration**

The research will last for a maximum of 16 weeks or from the time of the first visit with the nurse navigator to the last visit with the nurse navigator. Participating in this study will not take any additional time for you because the nurse navigator will likely ask you the same questions as part of their routine navigation assessment anyway.

**Risks**

Some risks might appear during the process. However, the healthcare workers will be looking after you and the other participants very carefully during the study. If you are concerned about what you are asked to answer as part of the research, you can remain silent, or you can say that you do not want to answer, or you can request to drop out of the study altogether.

**Benefits**

If you participate in this research there may not be any benefit for you personally, but your participation is likely to help us find answers to the research questions. The knowledge created through this study might help future cancer patients receive standardized care as promoted through the ONNPA© questionnaire.

**Reimbursements**

Your participation is free. You will not be given any money or gifts to take part in this research.

**Confidentiality**

We will not be sharing the identity of those participating in the research with anyone. The information that we collect from this research project will be kept confidential. Personal information about you will be put away and no-one but the researchers will be able to see your signature on the consent form. Instead of a name, your information will be linked to a number through a computer program. Only the researchers will have access to the computer program and can look up what your number is. The computer system will be locked with multiple secret passwords, that only the researchers will know. The passwords will not be shared with anyone else. There is an exception, that in rare circumstances, the federal research regulatory bodies and the Fort Lewis College Institutional Review Board may request access to the research records.

**Sharing the Results**

The knowledge that we get from doing this research will be shared with you by email if you want to review it before it is made available to the public. Confidential information will not be shared. After you had the chance to comment on the findings, we will publish the results so that other interested people may learn from the findings.

**Right to Refuse or Withdraw**

You do not have to take part in this research if you do not wish to do so. You may also stop participating in the research at any time you choose. It is your choice, and all of your rights will still be respected regardless.

**Alternatives to Participating**

If you do not wish to take part in the research, you will be provided with the facility-established nurse navigation assessment during your visits with the nurse navigator. In this sense, you will receive care as usual.

**Who to Contact**

If you have any questions, you may ask your nurse navigator or research team at the cancer center, even after the study has already started. If you wish, you may also contact Dr. Nora Flucke (970) 247-7188 or Colleen Sullivan-Moore (505) 203-5889 directly.

**This proposal has been reviewed and approved by the Fort Lewis College Institutional Review Board (IRB). The IRB is a committee whose task it is to make sure that research participants are protected from harm. If you want to find about more about our IRB process, please contact Becky Clausen (970) 247-7237 or Missy Thompson (970) 247-7580 at Fort Lewis College.**

You can ask me questions about any part of the research study if you wish. Do you have any questions at this time?

**PART II: Certificate of Consent**

**I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked, have been answered to my satisfaction. I consent voluntarily to take part as a participant in this research.**

**Print Name of Participant**_____

**Signature of Participant** _____

**Date** _____
**Day/month/year**

☐ I would like to be notified through my email _____of the study's results before it is published. Please send preliminary results to this email (optional).

**If illiterate or consenting through electronic communications**
A literate witness must sign. Participants who are illiterate should include their thumb-print as well. This witness may be the person obtaining consent but should not be part of the research team.

**I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.**

**Print name of witness**_____ **AND** **Thumb print of participant**

**Signature of witness** _____

**Date** _____
**Day/month/year**

**Statement by the researcher/person taking consent**
I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

☐ The participant is asked up to 42 questions as part of the ONNPA© questionnaire.

☐ The participant will work with the nurse navigator to reduce needs and barriers as usual.

☐ The participant will be asked selected questions of the ONNPA© questionnaire again as part of the re-assessment.

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.
A copy of this informed consent form has been provided to the participant.

**Print Name of Researcher/person taking the consent**_____

**Signature of Researcher /person taking the consent**_____

**Date** _____
**Day/month/year**