URCC 13059
Version Date 12/10/2015
Amendment #2

NCI Community Oncology Research Program – Kansas City (NCORP-KC)

Study Title for Study Participants:
Reducing Cancer Treatment Toxicity in Older Patients

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:
Protocol # URCC 13059: A Geriatric Assessment Intervention for Patients Aged 70 and Over Receiving Chemotherapy or Similar Agents for Cancer: Reducing Chemotherapy Toxicity in Older Patients

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Introduction:
You are being asked to take part in this study because you are a patient whose doctor is enrolled in a research study, and you are age 70 or older and are about to start a new cancer treatment plan.

A member of the research team will explain what is involved in this study. This consent form describes the study procedures, the risks and benefits of participation, as well as how your confidentiality will be protected. Please take your time to ask questions now or at a later time.

What is the usual approach to reducing toxicity in people receiving cancer treatment?
In this consent "cancer treatment" refers to chemotherapy as well as other cancer treatments allowed in this study that are similar to chemotherapy in their risk of side effects. There is currently no standard way for reducing the possible side effects that can happen from treatment for cancer. If your study doctor decides cancer treatment is appropriate for you and side effects occur, your study doctor will work to reduce the side effects per his/her usual care practice. This is most often done by reducing the amount or frequency of the cancer treatment, stopping the cancer treatment, switching to another treatment, and/or adding medications to treat side effects.

What are my other choices if I do not take part in this study?
If you decide not to take part in this study, you have other choices. For example:
- You may choose to receive usual care by your doctor.
- You may choose to take part in a different study, if one is available.

Why is this study being done?
A majority of patients diagnosed with cancer are over age 65, yet most cancer treatments are developed in a younger population. Older cancer patients are more likely to experience side effects. There is no standard way to treat cancer treatment side effects in older patients. A

Approval Date 2/8/2018 to 2/7/2019

Assurance#: FWA00003582

Geriatric Assessment (GA) can be used to predict who is at risk for side effects but there is no standard way to decrease this risk. Also, there is not agreement on how information from a GA can be used to develop ways to prevent or treat side effects.

The purpose of this study is to find out if the GA can help improve and develop a standard approach for reducing and/or preventing cancer treatment side effects in older cancer patients. The GA is intended to determine an older patient's level of independence taking into account health conditions, physical performance (walking, leg strength, and balance), nutrition, social support and memory. Several tests as well as questionnaires are used. The combined results establish what is called a patient's functional age, which may be quite different from the actual age. Functional age can help better predict a patient's tolerance of and likely response to cancer treatments as well as provide other important age-related information not routinely captured by cancer doctors. If you decide to participate in this study, you will receive the GA.

There will be about 700 people taking part in this study, at sites across the country.

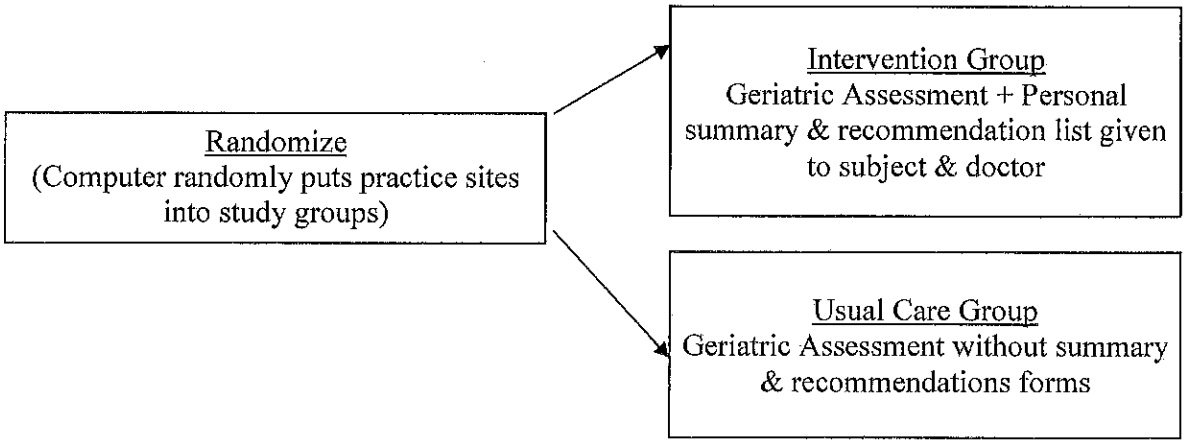
What are the study groups?

This study has two study groups. This study is part of a large national network called the University of Rochester NCI Community Oncology Research Program which includes practice sites where patients with cancer receive their care from oncologists, all across the country. The GA will be administered at practice sites in both study groups. The practice site where you see your doctor will be assigned (randomized), to either the usual care group or the intervention group. Randomization is the process where each practice site will be assigned to a study group by a process similar to flipping a coin. This is done because no one knows if one study group is better, the same, or worse than the other. Only the practice site is being randomized – not the subjects. Each subject that is recruited will follow the procedures for the group that the practice site is assigned to.

- **Intervention Group:** Subjects will complete the GA, which is composed of surveys, short physical, function, and memory tests. The GA results will be used to create a personalized health summary and recommendation list of treatments, which the study doctor can "use" prior to or during chemotherapy to try to reduce possible "side effects." The summary will be provided during the visit with the doctor just before the start of cancer treatment. The subject and study doctor will review the summary and recommendations to decide which of the recommendations will be started.

- **Usual Care Group:** Subjects will complete the GA, which is composed of surveys, short physical, function, and memory tests. The GA summary and recommendation list will NOT be given to subjects or their doctors in the usual care group. The cancer treatment plan and how to manage any possible "side effects" will be what subjects and their doctors decide.

Another way to find out what will happen to you during this study is to read the chart below. Start reading at the left side and read across to the right, following the lines and arrows.



How are the study groups formed? A computer will randomly assign the practice sites, where you see your doctor, to a study group. This is done because no one knows if one study group is better, the same, or worse than the other. Once you are put in one group, you cannot switch to the other group. In other words, if the subject is at a practice site which is in the usual care group, he/she cannot switch to the intervention group.

How long will I be in the study?

The total time in this study is approximately 6 months. You will be asked to complete the GA and surveys at the following times: prior starting a new cancer treatment plan during a screening and/or baseline visit (can be combined), and at 4-6 weeks, 3 months, and 6 months after starting a new cancer treatment plan. If you decide not to start a new cancer treatment plan before registering, your participation in this study is complete. Information about your medical care and health care use will be collected approximately 1 year after you enter the study.

What extra procedures are involved if I take part in this study?

Before you Begin the Study: You will review this document, and we will answer any questions you have. If you decide to participate, you will sign this document. We will give you a copy for your records and keep the original for our records.

During the Study: Your participation allows us to follow your initial visit with the study doctor and/or other members of the health care team, follow-up visits with members of the health care team, and the outcome of those visits. You may receive cancer treatment as prescribed by your doctor. Cancer treatments in this study are part of usual care and are determined by your doctor. The schedule, dose, and any changes in cancer treatment, how well it is tolerated, and how possible side effects are managed will be recorded.

Participation in the study includes the following:

- To participate in the study you must have at least one area of risk (other than medications) in the geriatric assessment.
- You will be asked to complete surveys that ask questions about your background, function, nutrition, medical problems, social support, memory and mental health before starting a new cancer treatment plan. Table 1 outlines the different survey topics and the times you will do them. Flexibility has been built in for completion of surveys; surveys can be completed during the office visit or taken home. The combined survey (screening/baseline) will take about 45 - 60 minutes at the beginning of the study and about 30 minutes at the other time points. Some questions will be asked by a trained research interviewer. Other questions you will complete on your own.

Table 1. Subject completed measures

Topic/Time Point	Screening or Baseline	4-6Wks	3 Mos.	6 Mos.
Demographics, social support and nutrition	x			
Memory & mental health	x	x	x	x
Functional and physical health	x	x	x	x
Making decisions	x	x	x	x
Subject reported side effects	x	x	x	x
Medication Review	x	x	x	x

- You will be asked to complete brief physical tests to assess your balance, walking, and leg strength.

- You will be asked to complete a short memory test by paper and pencil.

- A member of the research team will be available to help you complete surveys or other tasks, and answer any questions you may have.

- A research staff member will contact you during the study to see how you are doing and answer any questions you may have when completing the surveys before your next study visit.

After the Study: After you have completed the study, or if you decide to discontinue participating in parts of or all of the study, we would like to keep track of how well you are doing for approximately 1 year.

We would like to do this by reviewing your medical record to see how you are doing. By signing this consent, you are giving us permission to review your medical records as part of the study. You can ask us to stop reviewing your medical record for this study at any time.

We are also asking permission to access your claims information from the Centers for Medicare and Medicaid (CMS) services. This information will be utilized to review your use of different health care services in future research activities on health care utilization and costs of cancer care delivery. Please review the permission statement below:

"I give permission for my claim data to be requested from the Centers for Medicare and Medicaid Services (CMS). To make these requests we will need to collect your Medicare Beneficiary Number (this number will be your Social Security Number ;plus a code letter or your spouse's Social Security Number if they are deceased). This data may be used to look at cost effectiveness and/or other related research associated with the study's aims. Only data that is authorized for disclosure under the Privacy Act of 1974 and has been published as a System of Records (SOR) notice in the Federal Register will be available for release. The Privacy Act of 1974 and the published SOR notice are CMS' legal authorization to release the data and these legal requirements protect the confidentiality of individually identifiable data. All CMS data will be kept on a secure data server and only shared with study team members. The file will be password protected."

Please select an answer:

YES ____ NO ____

You may still participate in this study if you do not give us permission to obtain your information from Medicare. You can ask us to stop reviewing your medical record or Medicare claims information for this study at any time by noting your request in writing and giving it to your doctor, who will in turn give it to research team.

Your decision to participate in this study will not impact your overall care. It will permit us to follow your care and learn how your GA impacted decisions made by you and your doctor.

During this study, information about you will be collected for the purposes of this research. We will collect the results of your surveys as well as some information from your medical record including your name, dates of visits, information about your diagnosis and any previous treatment for cancer, current cancer treatments and any side effects, other medications, height and weight, and lab results. We will ask you to provide demographic information including date of birth, gender, race, ethnicity, income, and education.

All subjects will follow their routine visit schedules as designated by their health care team. This study will not affect the timing or details of those visits or any of your standard care.

What risks can I expect from being in the study?

Participation in this study involves the following potential risks:

- You may spend more time in the doctor's office than usual.
- You may become tired from filling out surveys or other study health evaluations.
- You may be asked questions which could cause you to become emotionally upset. If this occurs, your physician will be informed to help decide on how best to handle any concerns or issues. Support and counseling will be available from social workers, psychologists, and the principal investigator of the study as needed.

Confidentiality:
We have taken every precaution to safeguard your data by assigning you an ID number and not using your name. We will also protect electronic information on password-protected spreadsheets and documents within password-protected files and computers. Additionally, any paper copies of data are stored in locked cabinets within locked suites or facilities. All data that is shared will be free of personal identifying information. As you can see, we have taken every step to reduce the possibility of loss of confidentiality; however there is a very small possibility of loss of confidentiality when participating in any research study.

It is always your right to withdraw from a research study at any time with no penalty to your medical care at any institution you determine appropriate for care. If you wish to no longer share your data you may cancel (revoke) it in writing to the study investigator at any time. Information gathered before then may need to be used and given to others.

Will I benefit from this study?
This study may help researchers learn things that may help people in the future. This study will provide information that could help improve the care of future older patients facing cancer. If the study results are positive, oncologists may be more likely to more comprehensively evaluate overall health of an older patient with cancer using a GA in an effort to better address age-related concerns and the risks and benefits of cancer treatment.

Can I stop taking part in this study?

Yes, it is always your right to stop taking part in some or all aspects of the study. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study. If you choose not to continue participating in the study, it will not jeopardize your relationship or your ability to receive care from your doctor.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the NCI Community Oncology Research Program – Kansas City Institutional Review Board at 913-948-5588.

What are the costs of taking part in this study?

There are no costs to you for taking part in this study.

You and/or your health plan/insurance company will need to pay for all other costs of treating your cancer while in this study, including the cost of tests, procedures, or medicines to manage any side effects.

Will I be reimbursed for taking part in this study?

Assessments will be reimbursed at $15.00 each. Payment will be provided after each assessment time point (prior to the new cancer treatment plan, at the 4 to 6 weeks study visit, at the 3 month study visit, and at the 6 month final study visit).

What happens if I am injured or hurt because I took part in this study?

There is no anticipated risk for injury or harm to you as a result of this study. If you feel you have been injured or hurt as a result of taking part in the study, it is important that you tell the study doctor. You will get medical treatment if you are injured or hurt as a result of taking part in this study. Geriatric assessment is utilized in the care of older patients and has been shown to be safe.

The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance coverage, you would be responsible for any costs. Even though you are in a study, you keep all of your legal rights to receive payment for injury caused by medical errors.

Who will see my medical information?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. There are organizations that may inspect your records. These organizations are required to make sure your information is kept private. Some of these organizations are:

- The study sponsor, the University of Rochester and its affiliates in the NCI Community Oncology Research Program, the Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study
- Investigators at the University of Chicago and City of Hope who are helping to organize study procedures.
- The Department of Health and Human Services, the Food and Drug Administration and the National Cancer Institute in the U.S.

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can answer my questions about the study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number).*

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You will get a copy of this form. If you want more information about this study, ask your study doctor. You may also request a copy of the protocol (full study plan).

Release

By signing this form you authorize NCORP-KC to access and obtain information that is required for the study. This may include your medical records, labs, radiologic films and reports and pathology specimens. This authorization to disclose your medical records shall not expire, even upon death, unless specifically revoked in writing by you.

My Signature Agreeing to Take Part in the Study

Study Subject

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study and any additional research where I circled 'yes'.

Print Name _____

Signature_____

Date of signature_____/_____/_____

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____
Name and Title (Print)

_____ _____/_____/_____
Signature of Person Obtaining Consent Date

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Health Care Proxy Consent:
The subject on whose behalf I consent has left me named their health care proxy. My proxy decision on behalf of the subject conforms as closely as possible to what the subject would have done or intended under the circumstances. This decision takes into account what I believe are the subjects' personal, philosophical, religious, and/or moral beliefs and ethical values relative to the purpose of life, sickness, medical procedures, suffering, and death. I understand the study and have been encouraged to ask questions and have had my questions answered in full. I have received (or will receive) a copy of this document for mine and the subject's records and future reference.

_____
Name and Title (Print)

_____ / / _____
Signature of Health Care Proxy Date

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