URCC 13059
Physician Consent
Version date 12/10/2015
Amendment #2

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

Study Consent Information for Physician for:

Study Title for Study Participants (Physicians):
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 for Cancer or Similar Agents for Cancer: Reducing Chemotherapy Toxicity in Older Patients

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Introduction
We are asking you to participate in a research study. This text describes the research study and what you may expect if you decide to participate. Please read the following text carefully before you decide whether or not you want to take part in the research study. You may wish to print a copy of this for your files.

You are being asked to take part in this study because you are an oncologist caring for older patients with cancer within the University of Rochester NCI Community Oncology Research Program (NCORP).

Why is this study being done?
Although cancer is a disease of aging, older patients are underrepresented in clinical trials. Balancing the benefits against the risks of cancer treatment in the older patient population is challenging because of the dearth of evidence-based data to guide these decisions. Furthermore, older patients who are treated with cancer treatment are at high risk for adverse outcomes including serious toxicity and functional and physical consequences. The National Comprehensive Cancer Network (NCCN) guidelines advocate Geriatric Assessment (GA) for older patients with cancer to identify health status issues that increase the risk of adverse outcomes. A GA evaluates comorbidity, functional status, physical performance, cognitive ability, psychological status, medications and social support with standardized tools that predict morbidity and mortality in community-dwelling older adults. Our study will help oncologists implement GA and targeted recommendations for older patients with cancer receiving chemotherapy to see if toxicity is reduced.

For the purpose of this study, cancer treatment will be defined as chemotherapy (cytotoxic drugs); in addition, agents (e.g., monoclonal antibodies and targeted agents) that have a prevalence of grade 3-5 toxicity in older patients similar to chemotherapy (.50%) will be

allowed. A list allowable agents (single and in combination) meeting this toxicity criteria will be available on the URCC NCORP Research Base website as part of the study materials. Given the rapidly changing landscape of new drugs for cancer, the study team led by the PI will update the list accordingly after reviewing the toxicity profile of new therapies. **If the potentially eligible participant is to receive an approved drug or regimen not on the list, contact the URCC NOCRP Research Base study team for approval prior to participant enrollment.**

We estimate that approximately 300 physicians will participate.

What are the study groups?

NCORP sites will be randomized to usual care or the intervention. Individual physicians and patients will not be randomized. In other words, your practice location will determine whether or not you will be in the usual care group or the intervention group. A computer will randomly assign the practice sites 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 practices are put in one group, you cannot switch to the other group.

How long will I be in the study?

You will be in the study for as long as you decide to enroll patients. The planned duration of the study is 7 years.

What are the study procedures?

All study procedures will take place in your office or other private area (e.g. meeting room), according to your preference.

You will be asked to:

- Complete a 10-minute survey at the beginning and end of the project. The baseline surveys ask about demographic information, attitudes and your practice styles (situational vignettes). The follow-up survey will ask about your confidence in geriatrics and opinion on the GA (for intervention arm). These surveys can be completed online through a secure data management system called REDCap. You can complete this survey on paper if REDCap is not feasible.
  - REDCap will store and use your email address for surveys.
  - During this study, the study staff will collect information from you for the purposes of this research. In addition to your email address, the only personal identifying information you will provide will be your name, age, ethnicity, and the clinic you work in. You will be assigned a physician ID number, which will be used to link your surveys together with those of your patients enrolled in the study.
- Help to identify older patients with advanced cancer who are eligible for the study.
- For each of your patients who enroll, complete two brief surveys evaluating the decision to start a new chemotherapy regimen and the understanding of their disease. At the three follow-up visits complete a very brief survey regarding the decisions you made.

- Participate in a training session with the research team reviewing educational/training materials regarding GA, if you are affiliated with a site randomized to the intervention. This training session will be scheduled at a time that is convenient to you and will take approximately 20 minutes.

Study personnel at the University of Rochester NCORP Research Base will work with your office staff to identify eligible patients and to help ensure minimal disruption within your office.

What are the costs of taking part in this study?

There are no costs to this study.

Who will see my information?

The data you provide will be assigned a unique code number. All surveys and any study materials such as chart notes will be kept strictly confidential.

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 NCORP.
- The funding agency, National Cancer Institute.
- 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
- The University of Rochester Data and Safety Monitoring Committee
- 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.

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Who can answer my questions about the study?

You can talk to the principal investigator about any questions or concerns you have about this study or to report side effects or injuries. Contact the principal investigator Dr. Supriya Mohile, at 585-275-9319.

If you have any questions concerning your rights in this research study you may contact the University of Rochester's Institutional Review Board, which is concerned with the protection of subjects in research projects. You may reach the Human Subject Protection Specialist either by telephone at 585-276-0005; for long-distance you may call toll-free, 1-877-449-4441, or by writing: Research Subject Review Board, University of Rochester, Box CU 420315, 265 Crittenden Blvd, Rochester, NY 14642. You may also call this number if you cannot reach the research staff or wish to talk to someone else.

Agreeing to Take Part in the Study (for REDCap database survey consent)

Thank you for your consideration. By agreeing to participate in this study, you consent to the use and disclosure of information from your study materials as outlined in this study consent information form.

If you want to participate in the study, please select 'accept & consent' below.
If you do not want to participate in the study, please select 'decline' below.

By selecting 'accept & consent', you assert that you have read this subject consent information and agree to participate in the study.

<Language displayed (with "decline" or "accept & consent" buttons and ability to print out information).>

Physician Name _____

Date accepted _____

Thank you for learning more about this study!

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

Assurance#: FWA00003582