SWOG S1417CD
Revision 4
Version Date 11/21/2017

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

Consent Form for Primary Caregiver

Study Title for Study Participants:
Impact of Cancer on Finances

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:
S1417, "Implementation of a Prospective Financial Impact Assessment Tool in Patients with Metastatic Colorectal Cancer".

Why is this study being done?

Studies have shown that cancer patients may be at high risk for financial problems because of the cost of treatment. These financial problems can be stressful and sometimes might cause patients to avoid or refuse treatment. We want to measure how often financial problems happen in patients with colorectal cancer, using questionnaires that collect information about finances and quality of life. In order to get a full picture of the financial impact of colorectal cancer, we also want to collect credit reports for all patients in this study.

You have been asked to participate because_____ has identified you as their primary caregiver. _____ is participating in a **non**-treatment research study. As the primary caregiver, you will be asked to fill out a questionnaire that will capture your point of view about treatment, finances and caregiver duties. We also want to find out about caregivers in general therefore some of the questions may be about how you are related to the patient, your gender, age, race, etc. Our findings will hopefully give us a better understanding of the financial burden of cancer and help us develop ways to lessen the burden. Your participation is very important to this study.

There will be about 374 patients with metastatic colorectal cancer taking part in the study. We hope to capture an equal number of caregivers, though patients may still participate in the study even if their designated caregiver chooses not to.

What is the usual approach to use of medical information for research?

Hospitals and doctor's offices usually use a "Release of Medical Information" form to gather medical information from patients. Since the information we are requesting from you as a caregiver will not be in the patient's medical chart, we are using this consent form to inform you of the study and to get your permission to use the information you provide as part of the research data.

Approval Date 3/8/2018 to 2/7/2019

Assurance#: FWA00003582

What are my other choices if I do not take part in this study?

Participation in this study is optional.

How long will I be in this study?

You will be in the study for 12 months. Participation ends if you discontinue being the caregiver for the patient or choose to no longer participate.

What is involved?

If you agree to take part in the study, you agree to answer a questionnaire at each of the following times:

- at the time you and the patient agrees to be in the study (baseline)
- 6 months after the patient enters the study
- 12 months after the patient enters the study

It may take between 30 and 60 minutes to answer each questionnaire. You may fill out the questionnaires during the patient's clinic visit, at home, or over the phone. If you fill out the questionnaire at home, you can either mail it back to the research staff using a pre-addressed stamped envelope that we will provide, or you can bring it with you the next time you come to the clinic for the patient's appointment. The study staff will work with you to find the easiest option for you.

We will obtain the following information, directly from you (through questionnaires) and it will be included as part of the research data:

- Basic information about you, changes to your financial status, quality of life, your point of view on aspects of your dependent's cancer treatment.

What risks can I expect from taking part in this study?

You may feel uncomfortable being asked about your finances or physical and emotional health.

We have procedures in place to protect your personal information and we will do our best to make sure that the personal information used for this study will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will **not** be used.

To help make sure your information is private, your doctor or nurse will go to a secure data submission program sponsored by the National Cancer Institute (NCI) to send us your information. We can then go to the same secure program and get your information to include it with the information from all of the other patients taking part in the study.

What are the possible benefits of taking part in this study?

We hope to be able to use these questionnaires in the future to reliably capture financial hardship information in cancer patients and their caregivers.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study staff know as soon as possible. If you stop, you can decide whether or not to let the study staff continue to provide your information to the organization running the study.

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 or to the patient. You will not lose 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 associated with this study. The research staff will provide a stamped envelope if you choose to return questionnaires by mail. If you choose to do the questionnaire over the phone, the study staff will call you so that you do not incur long distance phone charges (if this applies to you).

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

There will be little risk of being injured on this study as it does not involve medical treatment.

Who will see my personal information?

Your privacy is very important to us and the researchers will make every effort to protect it. Your name or contact information will not be put in the database because this information will not be obtained from you. Your questionnaire responses will be entered under the participating patient's ID.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor, SWOG.
- 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 National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.
- Qualified representative(s) of the NCI Community Oncology Research Program (NCORP) Research Base with whom your institution is affiliated (Alliance, ECOG-ACRIN, NRG)

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 study 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 this study?

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

My Signature Agreeing to Take Part in the Study

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 this study.

Primary Caregiver _____

Primary Caregiver (Participant's) signature_____

Date of signature_____

Person obtaining consent _____

Signature of person obtaining consent _____

Date of signature _____