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

Consent Form

Project Title for Participants:

Collect Information to Understand Cancer Health Disparities and Clinical Trial Accrual

Official Project Title:

DCP-001, Use of a Clinical Trial Screening Tool to Address Cancer Health Disparities in the NCI Community Oncology Research Program (NCORP)

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be required. When we say "you" in this consent form, we mean you or your child; "we" means the doctors and other staff.

What is the usual approach to data collection

You are being asked to participate in a project that will collect the following information each time you are screened to participate in certain types of National Cancer Institute (NCI) clinical trials:

1) Reasons for not participating in a clinical trial.
2) Personal information and information about your cancer.

Outside of this protocol, NCI does not currently collect information on patients who are screened for a clinical trial.

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

If you decide not to take part in this study but are enrolled on an NCI clinical trial, you will have the usual data collected. If you are screened for an NCI clinical trial but do not enroll, no information will be collected and no other options are available.

Why is this project being done?

The purpose of this project is to understand who participates in clinical trials and for those who do not participate, the reasons why. This information will help researchers design future studies. Also, to address the reasons people do not participate, especially young adults and teenagers, older people and minorities. In addition, personal and medical information will be collected to help understand differences in treatment and treatment outcomes among these populations.

The data collected will be used by:

1) NCI to evaluate the overall performance of the community program (NCORP)
2) The medical team to better understand reasons patients don't participate, especially reasons related to the institution or the clinical trial
3) Researchers to improve the design of current and future studies
4) Researchers to develop research questions such as differences in access to care, treatment received and the outcome of the treatment received by different populations.

How many people will take part in the project?

There is no set number of people that will take part in this study.

What will happen on this project?

Members of your health care team have identified one or more NCI clinical trials you may be eligible for. At the time you undergo screening for the clinical trial or shortly thereafter, the health care team will obtain personal and clinical information from your medical record. The health care team will ask information that is not in your medical record. In some situations, a member of your healthcare team may ask these questions by phone. The information will be entered into a secure NCI clinical trial database. Each time you are screened for certain types of NCI clinical trial, data will be collected.

Who is included in the project?

All patients being screened for the following types of NCI clinical trials: late phase treatment, symptom or toxicity management, cancer care delivery, screening, prevention, observation and pre-cancer studies.

How long will I be in this project?

The data collection takes place each time you are screened for a clinical trial. The data collected will be stored and maintained at NCI for an unlimited period of time.

What extra tests will I have if I take part in this project?

Presently, NCI does not collect any data on patients screened for a clinical trial. This project will collect the following data each time a patient is screened for certain types of NCI clinical trials:

Gender
Race and ethnicity
Method of payment (insurance coverage)
Cancer diagnosis and stage
Marital status
Whether you live in a rural community
Income
Insurance at time of diagnosis

Employment status
Education
Method of diagnosis
Medical problems other than cancer
Reasons for not enrolling on a clinical trial (for example, did not meet the criteria, other medical conditions, insurance coverage, travel/transportation, no desire to participate in research)

In addition to the above information, your study doctor will collect your name, date of birth, and medical record number. This information will be used by your study doctor (at your treatment center) to review the data collected when you are screened for a clinical trial. Your study doctor will not share your name, date of birth, or medical record number with the study sponsor. The study sponsor will only have a special code, which they cannot use to identify you personally. If the study sponsor communicates with your cancer treatment team they will only know you as the special code and will not have access to your name, date of birth, and medical record.

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

No information collected by the Study Sponsor will be able to identify you personally. Your name, date of birth, medical record number, social security number, and address will only be collected by your study doctor and will not be made available to the Study Sponsor. Every effort will be made to keep your information private and confidential; however there is a rare chance you could be identified, especially if you have a rare type of cancer.

What possible benefits can I expect from taking part in this study?

You will unlikely benefit from this project. You will help researchers learn things to help other patients in the future. The information you provide will help researchers to:

1) Better understand who enrolls in clinical trials and why people do not participate in clinical trials.
2) Develop ways to improve participation.
3) Help medical practitioners understand how to care for certain populations while on a cancer clinical trial.
4) Help understand why some people do better than others when treated for cancer.

Can I stop taking part in this project?

Yes. You can decide to stop at any time and your information will be removed from the database.

What are my rights in this project?

Taking part in this project is your choice and completely voluntary. 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 project, call the Central Institutional Review Board at 888-657-3711.

What are the costs of taking part in this project?

There is no cost to taking part in this project and you will not be paid for taking part in this project.

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

This is a data collection project only; there is no chance of injury.

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. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

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 National Cancer Institute
- The Central Institutional Review Board, CIRB, is a group of people who review the research with the goal of protecting the people who take part in the study
- Researchers within the NCORP Program

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).

Who can answer my questions about this project?

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).*

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, radilogic 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.

You will get acopy of this form. If you want more information about this study, ask your study doctor.

My Signature Agreeing to Take Part in the Project

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 project.

I have reviewed the information and have had my questions answered.

I agree to take part in this project.

Participant_____

Participan signature_____

Date _____

Person obtaining consent _____

Person obtaining consent signature_____

Date of signature_____