S1714 Research Study Informed Consent Document

Study Title for Participants: Studying how cancer treatment affects the nerves in your hands and feet

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:

S1714, A Prospective Observational Cohort Study to Develop a Predictive Model of Taxane-Induced Peripheral Neuropathy in Cancer Patients

NCT# 03939481

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because treatments for your cancer can cause a problem with your nervous system (called peripheral neuropathy) that can lead to tingling or less feeling in your hands and feet.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

This study is being done to answer the following question:

Can we estimate how likely you are to develop the nerve disorder, peripheral neuropathy, based on certain risk factors, such as age, sex, pre-existing conditions, and the type of treatment you get for your cancer?

We are doing this study because we want to find out how each of the risk factors affects whether you develop the nerve disorder and whether it is possible to predict how likely patients are to develop it.

What is the usual approach to my cancer?

The usual approach for patients who are not in a study is treatment with medications for their cancer that have been approved by the Food and Drug Administration (FDA). Patients who are on this study will get the usual treatment for their cancer. Patients who are not on a study like this would not fill out forms about their risk factors and physical wellbeing.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.
- You may choose not to be treated for cancer.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will get treatment for your cancer in the same way as you will if you do not choose to take part in the study. Your doctor will discuss your treatment with you.

In addition to your regular cancer treatment, you will also provide the researchers with information about your risk factors for developing the nerve disorder and about your physical wellbeing. You will complete forms several times during the study that tell the researchers about your personal health and medical history (this will include information about your cancer, any other illnesses you might have, whether you have a history of falling), medications, supplements, or vitamins you take, your physical and emotional wellbeing before and during treatment, any

nerve issues you might experience, and your exercise habits. You will visit your doctor regularly so that they can evaluate you and provide medical information to the researchers. You will also provide blood samples when you begin the study and during your first chemotherapy treatment. You will have the option of providing blood samples at additional time points during the study.

You will take part in this study for three years.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the "What risks can I expect from taking part in this study?" section.

If you choose to take part in this study, there is a risk that you will be uncomfortable answering some of the questions in the forms, or that some of your personal information may be seen by others.

Benefits

This study is not likely to help you. However, it may help the study doctors understand how different risk factors and treatments affect whether cancer patients who receive chemotherapy develop the nerve disorder. This study may help the study doctors learn things that may help other people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible.

Your 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.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- **You do not follow the study rules.**
- **The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor (SWOG Cancer Research Network). The study sponsor is the organization who oversees the study.**

COMPLETE INFORMED CONSENT

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

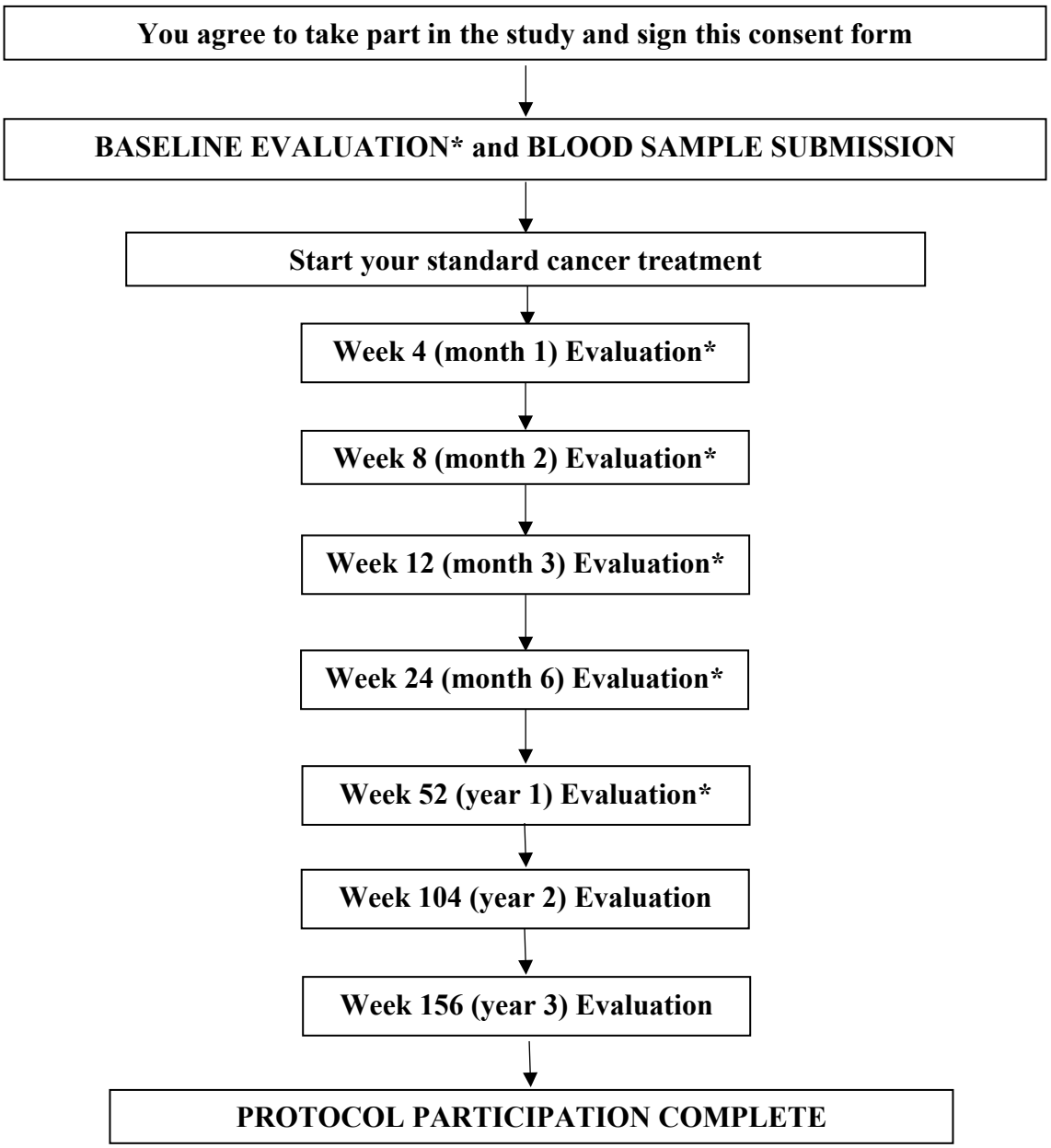
What is the purpose of this study?

You will be getting chemotherapy to treat your cancer. This treatment may cause a nerve disorder called peripheral neuropathy. The purpose of this study is to try to learn how certain risk factors, such as age, sex, pre-existing conditions, the type of treatment you get for your cancer, and the amount of cancer drugs in your body affect whether you develop the nerve disorder and how bad your symptoms will be. There will be about 1,310 people taking part in this study.

What are the study groups?

All patients on this study will get the standard treatment for your type of cancer that you would get if you were not on this study. In addition to the standard treatment for your type of cancer, all patients will (1) fill out forms several times that ask questions about your personal health and medical history (this will include information about your cancer, any other illnesses you might have, whether you have a history of falling), medications, supplements, or vitamins you take, your physical and emotional wellbeing before and during treatment, any nerve issues you might experience, and your exercise habits, and (2) provide blood samples so that researchers can look at how your genetics and levels of cancer drugs in your body affect whether you get the nerve disorder, and (3) take part in assessments from a member of your doctor's research team to look at your physical wellbeing, such as how easily you can move around.

Another way to find out what will happen to you during this study is to read the chart below. Start reading from the top and read to the bottom, following the lines and arrows.



* The evaluations will include the forms, blood samples, and assessments described in items (1), (2), and (3) above.

What exams, tests, and procedures are involved in this study?

The exams, tests, and procedures you need to see if you can take part in this study are all included in the usual care you would get even if you were not in a study. You will not have any additional exams, tests, or procedures to monitor your *safety* because of your participation in this study, but you will have additional procedures as part of the research study for other reasons that would not be included in usual care. These are outlined below.

Listed below are procedures that will be done for research purposes only.

Blood Samples

You will need to have blood samples taken for the study. About 2 tablespoons of blood will be taken for this main study blood draw when you first begin taking part in the study and just before you finish your first cycle of regular treatment for your cancer.

The specimens will be used to look at how the amount of cancer drugs in your body affect how likely you are to develop the nerve disorder. They will also be used to look at how different changes in your genes affect how likely you are to develop the nerve disorder.

This study will use genetic tests that may identify changes in the genes in your DNA. Your genes carry information about you and your family, from the color of your eyes to health conditions for which you may be at risk, such as certain kinds of cancer.

Finding these gene changes would not affect your treatment in this study. The results of these tests will not be given to you or your doctor.

You will have the option of providing additional blood samples over the course of the study; however, you will not be required to give these additional blood samples. This will be discussed more later in the consent form.

Forms and Assessments

If you choose to take part in this study, you will be asked to fill out forms with questions about your personal health and medical history (this will include information about your cancer, any other illnesses you might have, whether you have a history of falling), medications, supplements, or vitamins you take, your physical and emotional wellbeing before and during treatment, any nerve issues you might experience, and your exercise habits. Researchers will use this information to see how your personal health and medical history, medications, and physical and emotional wellbeing affect how likely you are to develop the nerve disorder.

Since these forms are being used for research, the responses you provide will not be shared with your study doctor. If you have any serious health issues or other concerns at any time during the study, please talk with your doctor or nurse right away.

You will be asked to fill out 2-6 forms while you take part in this study. You will fill out forms at 8 times:

- When you first sign up for the study
- About 1 month after you join the study
- About 2 months after you join the study
- About 3 months after you join the study
- About 6 months after you join the study
- About 12 months after you join the study
- About 24 months (2 year) after you join the study
- About 36 months (3 year) after you join the study

It will take between about 20 to 35 minutes for the first 12 months to complete all of the forms each time. It will take between about 10-15 minutes to complete all of the forms at the 24 month and 36-month time points. You don't have to answer any question that makes you feel uncomfortable.

A member of your doctor's research team will also give you several assessments to provide the researchers with information about your cancer treatment, side effects of your cancer treatment, how you react to pressure and sharpness (with a Neuropen), and how well you feel vibration (with a tuning fork).

These assessments will be done when you first sign up for the study and at 1, 2, 3, 6, and 12 months after you join the study. The Neuropen assessment involves touching a small piece of plastic (called a monofilament) and a small sharp pin (called a Neurotip) to the bottom of your foot to see if you can feel pressure and sharpness. The tuning fork assessment involves touching a tuning fork to several places on your leg and arm to see if you can feel vibration.

A member of your doctor's research team will also assess how well you are able to move and whether you are at higher risk of falls. This will be done when you first sign up for the study and at 6 and 12 months after you join the study.

Researchers will also use the information from these assessments to see how it affects how likely you are to develop the nerve disorder.

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

General Risks

You may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- Having blood drawn. The most common risks related to having blood drawn from your arm are brief pain and maybe a bruise. Because you are already having blood drawn as part of your cancer treatment, this will not be an additional risk.

Forms and Study Assessment Risks

There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.

There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your study appointments.
- Complete study forms and assessments
- Tell your doctor about
    - all medications and supplements you are taking
    - any side effects
    - any doctors' visits or hospital stays outside of this study
    - if you have been or are currently in another research study.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get to treat your cancer, as cancer treatment is not part of this study.

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

- The assessments to check your nerves (Neuropen to test your response to pressure and sharpness and tuning fork to test your response to vibration).

- Submission of blood and the tests that will be done with the blood.

Taking part in this study may mean that you need to make more visits to the clinic or hospital or to spend more time at the clinic or hospital each time than if you were getting the usual approach to treat your cancer. You may:

- Have more travel costs.
- Need to take more time off work.
- Have other additional personal costs.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

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

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- The study sponsor (SWOG Cancer Research Network) and any company supporting the study now or in the future.
- The IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The FDA and the groups it works with to review research.
- The NCI and the groups it works with to review research.
- The NCI's National Clinical Trials Network and the groups it works with to conduct clinical trials.

Your study records also will be stored for future use. However, your name and other personal information will not be used. Some types of future research may include looking at your records and those of other patients to see who had side effects across many studies or comparing new study data with older study data. However, we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

There are laws that protect your genetic information. However, there is a risk that someone could get access to your genetic information and identify you by name. In some cases, employers could use your genetic information to decide whether to hire or fire you. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about the laws that protect you, ask your study doctor.

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.

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, and email address if appropriate*)**.

For questions about your rights while in this study, call the **(*insert name of organization or center*)** Institutional Review Board at **(*insert telephone number*)**.

Optional studies that you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. They are separate from the main study described above. These optional studies will not benefit your health. The researchers leading these optional studies hope the results will help other people with cancer in the future. The results will not be added to your medical records and you or your study doctor will not know the results.

Taking part in these optional studies is your choice. You can still take part in the main study even if you say "no" to these studies. There is no penalty for saying "no." You and your insurance company will not be billed for these optional studies. If you sign up for, but cannot complete these studies for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for the following studies.

1. **Contact for Future Research**

   I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

   YES NO

2. **Optional sample collections for known laboratory studies and/or storage for possible future studies**

   (Please read this section and circle your response at the end.)

   Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

   Some of these studies may be about how genes affect health and disease. Other studies may look at how genes affect a person's response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of the studies may lead to new products, such as drugs or tests for diseases.

Unknown future studies

If you choose to take part in this optional study, researchers will collect and store blood from a vein in your arm. These samples will be collected at the same time as the study blood draws or during your cancer treatment blood draws. Storing samples for future studies is called "biobanking." The biobank is being run by Nationwide Children's Hospital and is supported by the NCI. Also, any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will be stored for future use.

We don't know what research may be done in the future using your stored blood samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- Future research studies may include sequencing of all or part of your DNA called genomic sequencing. All your genetic information makes up your genome. Genomic sequencing is a test that records all or part of the pieces of DNA that are in your genes, piece by piece. This is usually done to look for changes in your genome that may cause health problems.
- You will not get reports or other information about any research that is done using your samples.

What is involved in this optional sample collection?

If you agree to take part, here is what will happen next:

1. About 2 tablespoons of blood will be collected from a vein in your arm when you first begin taking part in the study and just before you finish your first cycle of regular treatment for your cancer. This was discussed earlier as part of the main study blood draw and will be collected for all patients. It will only be stored for future research with your permission. We are also asking your permission to collect and store about 1 ½ tablespoons of blood will be taken at the following times:
    - about 1 month after you join the study
    - about 2 months after you join the study
    - about 3 months after you join the study
    - about 6 months after you join the study
    - about 12 months after you join the study

Whenever possible, blood will be drawn at the same time blood is being drawn as part of your regular cancer care.

2. Any blood left over after the testing described above is finished will be stored in the biobank. Left over blood from the main study blood draws will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
3. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.
4. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in this optional sample collection?

- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is very small. However, the risk may increase in the future as people find new ways of tracing information.
- In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/.

How will information about me be kept private?

Your privacy is very important to the study researchers and biobank. They will make every effort to protect it. Here are just a few of the steps they will take.

1. They will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to patient identifiers, but they will keep it separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.

3. Your personal information will not be given to anyone unless it is required by law.
4. If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in this optional sample collection?

You will not benefit from taking part.

The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are there any costs or payments to this optional sample collection?

There are no costs to you or your insurance. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What if I change my mind about this optional sample collection?

If you decide you no longer want your samples to be used, you can call the study doctor, **(*insert name of study doctor for main trial*)**, at **(*insert telephone number of study doctor for main trial*)**, who will let the biobank know. Then, any sample that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I have questions about this optional sample collection?

If you have questions about the use of your samples for research, contact the study doctor, **(*insert name of study doctor for main trial*)**, at **(*insert telephone number of study doctor for main trial*)**.

Please circle your answer below to show if you would or would not like to take part in each optional study:

Samples for future studies:

My samples and related information may be kept in a Biobank for use in future health research.

YES **NO**

This is the end of the section about optional studies.

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 and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies where I circled "yes".

Participant's signature_____

Date of signature_____

Signature of person(s) conducting the informed consent discussion

_____

Date of signature_____