



Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

Protocol Title: Yoga for Painful Chemotherapy-Induced Peripheral Neuropathy: A Pilot, Randomized-Controlled Study

DF/HCC Principal Research Doctor / Institution:

Robert Knoerl PhD, RN, Dana-Farber Cancer Institute

DF/HCC Site-Responsible Research Doctor(s) / Institution(s):

Robert Knoerl PhD, RN, Dana-Farber Cancer Institute

Main Consent

INTRODUCTION AND KEY INFORMATION

All research is voluntary. It is your choice whether you take part in this research or not.

The following is a short summary of this research study to help you decide whether you would like to be a part of this study. More detailed information is provided later in this form.

For purposes of this research, you will be referred to as a “participant.”

1. Why am I being invited to take part in a research study?

You are invited to take part in in this research study, because you have painful chemotherapy-induced peripheral neuropathy that has persisted for at least three months after the completion of chemotherapy treatment. You may have symptoms of chemotherapy-induced peripheral neuropathy if you experience numbness, tingling, or pain in your hands or feet after chemotherapy treatment.

2. Why is this research being done?

This research study will examine the feasibility of conducting an eight-week yoga intervention for individuals with chronic painful chemotherapy-induced peripheral neuropathy. We will also explore participants’ perceptions of acceptability and

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRs 10.29.2019

satisfaction with the yoga intervention. Lastly, we will examine changes in chemotherapy-induced peripheral neuropathy severity, physical function, sleep-related impairment, fatigue, anxiety, depression, pain, and salivary cortisol following the eight-week yoga intervention.

3. What does this research study involve and how long will it last?

This research study involves questionnaires/tests, specimen collection, yoga.

This research involves the collection of salivary cortisol specimens. Cortisol is a hormone in your body that is released when you are stressed and helps to decrease inflammation. A specimen refers to a sample that is used for medical testing. In this study, we will collect a saliva sample and test your saliva for the presence of cortisol. The salivary cortisol samples will be analyzed at the Brigham Research Assay Core. However, depending on when you consent to the study, salivary cortisol collection may not be apart of the study due to COVID-19.

The name of the intervention involved in this study is yoga.

The research study procedures include screening for eligibility, saliva specimen collection, and study treatment (yoga) including evaluations and follow up visits.

You will be in this research study for approximately 10-12 weeks. You may receive the yoga intervention for up to eight weeks.

It is expected that about 50 people will take part in this research study.

Information about you and your health is personal and private. Generally, it cannot be obtained without your written permission. By signing this form, you are providing that permission and your information may be obtained and used in accordance with this informed consent and as required or allowed by law. This means that researchers may obtain information regarding your past medical history, as well as specimens and samples from previous health care providers such as hospitals and labs.

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRs 10.29.2019

4. What are the risks to participating in this study?

There are risks to taking part in any research study.

Major known risks to participating in this research study include:

- Disclosure of personal information may result in a loss of privacy
- Possible emotional distress due to personal questions or saliva collection
- Significant amount of time required to complete questionnaires (online and/or in person)
- Significant amount of time required to attend yoga classes
- Injury from participating in the yoga program

5. Will being in this study benefit me in any way?

We do not know if taking part in this study will benefit you. This study may help researchers learn information that could help people in the future.

6. What are my options?

If you decide to participate, please sign and date at the end of this form.

We will give you a copy and you can refer to this consent form at any time during the research study.

If you choose not to participate in this research study, the research doctors will discuss other treatment options with you and/or refer you to your primary doctor.

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRs 10.29.2019

A. WHY IS THIS RESEARCH STUDY BEING DONE?

This research study is a Pilot-Feasibility Study, which is the first-time investigators are examining yoga for chronic painful chemotherapy-induced peripheral neuropathy.

In this research study, we are:

- Examining the feasibility of implementing an eight-week yoga intervention for individuals with chronic painful chemotherapy-induced neuropathy
 - Yoga interventions have been previously tested in patients with other chronic pain conditions (like low back pain or fibromyalgia).
 - The yoga classes we are offering in this study are a part of the regular yoga classes offered by the Zakim Center at Dana-Farber Cancer Institute.
- Evaluating changes in chemotherapy-induced peripheral neuropathy severity, physical function, sleep-related impairment, fatigue, anxiety, depression, pain, and salivary cortisol following the yoga intervention.

B. WHAT OTHER OPTIONS ARE THERE?

Instead of being in this research study, you have other options which may include the following:

- Decide not to participate in this research study.
- Participate in another research study.

If you choose not to participate, are not eligible to participate, or withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions now and in the future.

C. WHAT IS INVOLVED IN THE RESEARCH STUDY?

Before the research starts: Prior to signing this consent form, you will be asked to answer some questions or undergo some screening tests or procedures to find out if you can be in the research study.

- **A medical history**, which includes questions about your health, current medications, and cancer history

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRS 10.29.2019

- **Medical record review**, which will include a review of your previous and planned chemotherapy regimens, documentation of peripheral neuropathy prior to starting chemotherapy, documentation of psychiatric diagnosis
- We will ask you about your current yoga practice
- We will ask you to rate your worst chemotherapy-induced peripheral neuropathy pain intensity over the past week

If these tests show that you are eligible to participate in the research study, you will be eligible to participate in the research study. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

After the screening procedures confirm that you are eligible to participate in the research study:

Table 1 describes the surveys/tests that will be completed by you at every visit associated with the study and the approximate amount of time that it will take you to complete the surveys (surveys and tests administered may vary depending on which study group you are assigned to). If you do not want to answer specific questions for whatever reason, you are able to do so.

Study Visit: Baseline

Before beginning the study, you will complete several surveys that ask about different symptoms you may be experiencing. This will take about 30 - 40 minutes to complete and will be done at the clinic or via email.

In the week following the completion of the initial surveys at the clinic, you will keep track of your worst chemotherapy-induced peripheral neuropathy pain score every day for seven days. At the end of the seven days, you will report your scores to the study team.

In addition, you will provide six saliva samples at three different times over the course of two days using the materials we provide you: 1) when you wake up, 2) 30 minutes after waking up, and 3) when you go to bed. You will ship all the samples in a pre-paid mailing box to the Brigham Research Assay Core.

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
 BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRS 10.29.2019

This visit will involve the following:

- **Questionnaires or Surveys:** Chemotherapy-Induced Peripheral Neuropathy Worst Pain Intensity, Pain Interference (how much pain interferes with daily activities), Physical Function, Fatigue, Neuropathy Severity (numbness and tingling), Depression, Anxiety, Sleep Problems, Demographics, Exercise, Medication Use.
- **Saliva Samples:** You will provide six saliva samples over the course of two days at home.

Table 1: Study Calendar

Data Collection Tool	Time to Complete	Baseline	Weekly	End of Study
<i>Self-Report Measures</i>				
Chemotherapy-Induced Peripheral Neuropathy Pain Intensity	< 1 minute	X		X
Pain Interference	1 – 4 minutes	X		X
Physical Function	1 – 4 minutes	X		X
Fatigue	1 – 4 minutes	X		X
Depression	1 – 4 minutes	X		X
Anxiety	1 – 4 minutes	X		X
Sleep Problems	5 minutes	X		X
Neuropathy Severity	10 minutes	X		X
Demographics	5 minutes	X		
Medication Use	5 minutes	X		X
Exercise Questions	5 minutes	X	X	X
<i>Sample Collection</i>				
Salivary Cortisol Collection	30 minutes	X		X
<i>Semi-Structured Interview</i>				
Interview about experience with yoga program	60 minutes			X

After you complete most of the baseline measures, you will be placed into one of two different treatment groups. The decision about which group you will be in will be based on chance, like flipping a coin. The process of placing you into the treatment groups is called “randomization” and is generally done by computer. Both groups in this study will continue to receive treatment from their usual care providers, however, one group will participate in an eight-week yoga program. A

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRs 10.29.2019

study team member will call you to notify you of your study group assignment and to see how it is going with the surveys and saliva sample collection.

Intervention: Yoga

Table 2 outlines a sample of the yoga exercises you may practice during the study. The Zakim Center at Dana-Farber Cancer Institute offers several yoga classes a week (Chair Yoga Flow or Gentle Flow Yoga). As part of this study, the participant is asked to attend these classes during the eight-week intervention period either in-person at the Zakim Center or virtually using Zoom. Each class is 45 minutes in length and is led by certified yoga therapists with oncology experience. In addition, you will receive access to self-guided videos of the yoga classes to practice on your own (vary in length). We hope you attend at least two yoga classes per week. During the study, you will keep track of how often you attend in-person or virtual yoga classes and how often you practice yoga or other exercises or self-management strategies on your own. Based on this information, study staff or the yoga instructor will attempt to call you each week to discuss your goals and barriers associated with yoga practice. Overall, the yoga classes/videos consist of: 1) guided breathing exercises, 2) upper/lower extremity stretching, and 3) structured postures, balance training, and movements.

Table 2: Yoga Class Sample

Activities
<ul style="list-style-type: none"> • Awareness <ul style="list-style-type: none"> • <i>Therapist will lead class participants in a mindful body scan and structured meditation exercises (i.e., guided breathing)</i>
<ul style="list-style-type: none"> • Warm up: <ul style="list-style-type: none"> • <i>Therapist will lead the class in structured stretches and massages to loosen up muscles and joints</i> • <i>Activities include</i> <ul style="list-style-type: none"> ○ <i>Shoulder and neck rolls</i> ○ <i>Spine and core twists, rolls, tilts, extension, and flexion</i> ○ <i>Hip, knee, ankle, feet and toe stretches</i> ○ <i>Arm, elbow, wrist, hand, and finger stretches</i>
<ul style="list-style-type: none"> • Flow <ul style="list-style-type: none"> • <i>Therapist will lead participants in guided movements with the goal of connecting breath and movement</i>
<ul style="list-style-type: none"> • Deep Stretching <ul style="list-style-type: none"> • <i>Therapist will lead participants in deeper (hold for longer period of time) upper and lower body stretches</i>

Page 7 of 19

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRS 10.29.2019

- | |
|---|
| <ul style="list-style-type: none"> • Closing <ul style="list-style-type: none"> • <i>Therapist will provide education on the connection between mindfulness breath and stillness</i> |
|---|

Control: Treatment-as usual

If you are randomized to the control group, you will continue to receive treatment as usual from your oncology provider. You will be asked to not participate in any yoga classes at Dana-Farber Cancer Institute and to not increase the current amount of time you spend practicing yoga each week. After you complete all study-related activities, you will be encouraged to attend the in-person or virtual yoga classes at the Zakim Center at Dana-Farber Cancer Institute and will receive access to the self-guided yoga videos. You will complete all the assessments in Table 1 except for the interviews at the end of the study and the weekly exercise questions (you will still answer exercise questions at baseline and at the end of the study).

Study Visit: Weekly (intervention group only)

Each week after beginning the yoga intervention, you will keep track of how often you are practicing yoga or other exercises.

This visit will involve the following:

- **Questionnaires or Surveys:** Self-monitoring and reporting of exercise and yoga use

Study Visit: End of study

Approximately ten weeks after the baseline assessment, you will complete several surveys that ask about different symptoms you may be experiencing. This will take about 30 - 40 minutes to complete and will be done at the clinic or using email.

You will keep track of your worst chemotherapy-induced peripheral neuropathy pain score every day for seven days. You will enter in your seven-day pain scores into an electronic survey or over the phone.

In addition, you will provide six saliva samples at three different times over the course of two days using the materials we provide you: 1) when you wake up, 2) 30 minutes after waking up, and 3) when you go to bed. You will ship all the samples in a pre-paid mailing box to the Brigham Research Assay Core.

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRs 10.29.2019

This visit will involve the following:

- **Questionnaires or Surveys:** Chemotherapy-Induced Peripheral Neuropathy Worst Pain Intensity, Pain Interference (how much pain interferes with your daily activities), Physical Function, Fatigue, Neuropathy Severity (numbness and tingling), Depression, Anxiety, Sleep Problems, Medication Use, Exercise.
- **Saliva Samples:** You will provide six saliva samples over the course of two days at home.

After the final intervention:

Research staff will go into your electronic medical record and record data related to your cancer diagnosis and treatment.

Individuals randomized to the yoga group will have an opportunity to participate in a 60-minute semi-structured interview to tell us their overall satisfaction and experience with the yoga program. Not all participants randomized to the yoga group will participate in the interviews as we expect that we will begin to hear similar feedback after approximately ten interviews.

D. WHAT ARE THE RISKS OR DISCOMFORTS OF THE RESEARCH STUDY?

You may experience distress when answering the questions in the surveys or providing saliva samples. If you do, you can talk to your health care providers in the clinic, and they may refer you for special support, such as counseling. You may also experience a physical injury from participating in the yoga program. The yoga program will involve stretching, balance, and strength training. If you do, we will refer you to your primary care provider or oncologist to discuss treatment. You can also contact the study principal investigator whose contact information is listed below if you experience any harm from participating in this study.

You may also be concerned about the privacy of the information you report in this study. All information you provide to the study team will be stored in locked file cabinets at Dana-Farber Cancer Institute. Only the research team will be able to see the information you report.

Risks of Biobanking:

Generally, hospitals will keep some of your saliva sample. This saliva sample may be used to help treat your cancer in the future. There is a small risk that

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRs 10.29.2019

when this sample is submitted to the biobank for this optional sample collection, your saliva sample could be used up.

E. WHAT WILL HAPPEN IF I AM REMOVED FROM THE STUDY OR DECIDE TO END MY PARTICIPATION IN THE RESEARCH?

You may be taken off the research study for any reason including:

- It is considered to be in your best interest
- The study treatment or procedures are found to be unsafe or ineffective
- There is any problem with following study treatments and procedures
- Your condition worsens
- A decision is made to end the study
- Or for other unforeseen reasons that make it necessary to stop your participation in the research study

You can also choose to stop participating in the research study at any time. Tell the research doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop. Leaving the research study will not affect your medical care outside of the research study.

It is important to tell the research doctor if you are thinking about stopping so your research doctor can evaluate the risks from stopping the yoga program.

Identifiable information related to samples and/or data will be destroyed after all analyses are complete. We only plan on keeping deidentified samples and/or data after the completion of the study.

If you decide to withdraw from a study that involves de-identified samples and/or data, it will not be possible to remove the samples and/or data that have already been submitted to a database or biobank.

F. WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?

You will be reimbursed for your parking expenses when you come to Dana-Farber for follow up study visits (both study groups) or yoga classes (intervention group only) that are not associated with your usual medical care.

We may use your samples and information to develop a new product or medical test to be sold. The sponsor and hospital may benefit if this happens. There are no plans to pay you if your samples are used for this purpose.

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRs 10.29.2019

G. WHO IS SUPPORTING THIS RESEARCH?

Oncology Nursing Foundation is supporting this research study by providing money for the equipment and supplies used in this study.

H. WHAT ARE YOUR COSTS?

Taking part in this research study will not lead to added costs to you or your insurance company

You or your insurance company will be charged for portions of your care during this research study that are considered standard care. Standard of care is the care that you would receive regardless of whether you were enrolled in the study or not. You may be responsible for co-payments, co-insurance, premiums and deductibles that are typical for your insurance coverage. This includes the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests, done for research only, are supplied at no charge.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services for information. The contact information for financial services are:

- Dana-Farber Cancer Institute: (617) 632-3455

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below or can be provided by the study team:

www.cancer.gov
or 1-800-4-CANCER (1-800-422-6237)

I. WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?

If you think you have been injured as a result of taking part in this research study, tell the person in charge of this research study as soon as possible. The research doctor's name and phone number are listed in this consent form.

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRs 10.29.2019

The treating hospital will offer you the care needed to treat injuries directly resulting from taking part in this research. These treatments may be billed to you or your insurance company. You will be responsible for deductibles, co-payments and co-insurance. There are no plans to pay you or give you other compensation for the injury.

You do not give up your legal rights by signing this form.

We will need to collect certain personal information about you for insurance or payment reporting purposes, such as your name, date of birth, gender, social security number or Medicare identification number and information related to this research study. We may be required to report this information to the Centers for Medicare & Medicaid Services. We will not use this information for any other purpose.

If you go to the Emergency Room or to another hospital or doctor it is important that you tell them that you are in this research. If possible, you should give them a copy of this consent form.

J. WHOM DO I CONTACT IF I HAVE QUESTIONS ABOUT THE RESEARCH STUDY?

If you have questions about the study, please contact the research doctor or study staff as listed below:

Dana-Farber Cancer Institute

- Robert Knoerl, PhD: (617-632-6386)

24-hour contact: Dana-Farber Cancer Institute: Robert Knoerl, PhD, at 734-536-9369

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at Dana-Farber Cancer Institute (617) 632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study.

K. RETURN OF RESEARCH RESULTS

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRs 10.29.2019

information or samples gives results that do have meaning for your health, the researchers may contact you to let you know what they have found.

L. CLINICALTRIALS.GOV (CT.GOV)

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.

M. FUTURE USE OF DATA AND SPECIMENS

Your personal information and/or biospecimens collected during this study may be stored and used for future research. Any personal identifiers will be removed so that the information or samples cannot be linked back to you. As a result, we will no longer be able to identify and destroy them.

Investigators, including investigators from collaborating institutions, can request this data and samples for new research. Samples and data may also be shared with outside non-profit academic investigators as well as with for-profit pharmaceutical investigators or commercial entities, with whom we collaborate.

You will not be asked to provide additional informed consent for the use of your de-identified information or samples in future research.

Future research studies may include genetic research. Your genes are unique to you. At this time, you cannot be identified through this research. There is a risk that you might be reidentified in the future as genetic research progresses

N. CONFIDENTIALITY

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

Participation in this study involves providing a specimen of your tissue; please know that if the research doctor leaves the institution, the research and the tissue might remain at the DF/HCC or might be transferred to another institution.

The study team plans to publish the results of this research study and when we do, we may be asked to make the data we collect available to other researchers.

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRs 10.29.2019

We will not include information that identifies you in any publications or to the researchers who request the data to do additional research.

Your de-identified specimens or genetic data may also be placed into one or more publicly-accessible scientific databases. Through such databases, researchers from around the world will have access to de-identified samples or data for future research.

There is a risk that deidentified research data that is shared with outside collaborators may be reidentified. When deidentified data and specimens are shared with outside collaborators agreements limit what the outside collaborators can do with the information to help prevent reidentification.

O. GENETIC RESEARCH

This research will not involve genomic or germline testing.

P. PRIVACY OF PROTECTED HEALTH INFORMATION (HIPAA AUTHORIZATION)

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research doctors, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions (“protected health information”). If you enroll in this research study, your “protected health information” will be used and shared with others as explained below.

1. What protected health information about me will be used or shared with others during this research?

- Existing medical records, including mental health records.
- New health information created from study-related tests, procedures, visits, and/or questionnaires

2. Why will protected information about me be used or shared with others?

The main reasons include the following:

- To conduct and oversee the research described earlier in this form;
- To ensure the research meets legal, institutional, and accreditation requirements;

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRS 10.29.2019

- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm); and
- To provide the study sponsor with information arising from an adverse event or other event that relates to the safety or toxicity of the drug(s) used in the study and for the purpose of this or other research relating the study drug(s) and their use in cancer;
- To better understand the diseases being studied and to improve the design of future studies; and,
- Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given a notice for use and sharing of protected health information.)

3. Who will use or share protected health information about me?

- DF/HCC and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

4. With whom outside of DF/HCC may my protected health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as analysis by outside laboratories on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor(s) of the study, its subcontractors, representatives, business partners, and its agent(s): Oncology Nursing Foundation
- Other research doctors and medical centers participating in this research, if applicable
- Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRS 10.29.2019

necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.

- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable

Some who may receive your protected health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

5. For how long will protected health information about me be used or shared with others?

- There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

6. Statement of privacy rights:

- You have the right to withdraw your permission for the research doctors and participating DF/HCC entities to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: "Whom do I contact if I have questions about the research study?"
- You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: "Whom do I contact if I have questions about the research study?"

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRs 10.29.2019

Q. DOCUMENTATION OF CONSENT

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study;
- I have been told that my participation is voluntary and I can withdraw at any time

Signature of Participant
or Legally Authorized Representative

Date

Relationship of Legally Authorized Representative to Participant

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
Date Posted for Use: 05/21/2020	

Research Consent Form

Dana-Farber/ Harvard Cancer Center
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRs 10.29.2019

To be completed by person obtaining consent:

Adult Participant

The consent discussion was initiated on _____ (date).

Signature of individual obtaining consent: _____

Printed name of above: _____

Date: _____

A copy of this signed consent form will be given to the participant or legally authorized representative.

1) The participant is an adult and provided consent to participate.

1a) Participant (or legally authorized representative) is a non-English speaker and signed the translated Short Form in lieu of English consent document:

As someone who understands both English and the language spoken by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.

Signature of Interpreter/Witness: _____

Printed Name of Interpreter/Witness: _____

Date: _____

1b) Participant is physically unable to sign the consent form because:

The participant is illiterate.

The participant has a physical disability.

Other (please describe): _____

The consent form was presented to the participant who was given the opportunity to ask questions and who communicated agreement to participate in the research.

Signature of Witness: _____

Printed Name of Witness: _____

Date: _____

DFCI Protocol Number: 18-578	Approved Date (DFCI IRB Approval): 05/19/2020
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OHRS 10.29.2019

- 2) The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:
 - 2a) gave permission for the adult participant to participate
 - 2b) did not give permission for the adult participant to participate

To be completed by person obtaining consent:

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